S. Hrg. 99-368

RADIOEPIDEMIOLOGICAL TABLES

JOINT HEARINGS

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES

AND THE

SUBCOMMITTEE ON NUCLEAR REGULATION

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

REVIEW OF THE POSSIBLE MEDICAL CONSEQUENCES WHICH MAY ARISE FROM THE USE OF RADIOEPIDEMIOLOGICAL TABLES, FOCUSING ON SECTION 7(b) OF PUBLIC LAW 97-414

JUNE 11 AND 12, 1985

Printed for the use of the Committee on Labor and Human Resources

---

U.S. GOVERNMENT PRINTING OFFICE
55-750 O WASHINGTON : 1986

S321-10
S541-16

COMMITTEE ON LABOR AND HUMAN RESOURCES

ORRIN G. HATCH, Utah, *Chairman*

ROBERT T. STAFFORD, Vermont
DAN QUAYLE, Indiana
DON NICKLES, Oklahoma
PAULA HAWKINS, Florida
STROM THURMOND, South Carolina
LOWELL P. WEICKER, Jr., Connecticut
MALCOLM WALLOP, Wyoming
CHARLES E. GRASSLEY, Iowa

EDWARD M. KENNEDY, Massachusetts
CLAIBORNE PELL, Rhode Island
HOWARD M. METZENBAUM, Ohio
SPARK M. MATSUNAGA, Hawaii
CHRISTOPHER J. DODD, Connecticut
PAUL SIMON, Illinois
JOHN F. KERRY, Massachusetts

RONALD F. DOCKSAI, *Staff Director*
KATHRYN O'L. HIGGINS, *Minority Staff Director*

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ROBERT T. STAFFORD, Vermont, *Chairman*

JOHN H. CHAFEE, Rhode Island
ALAN K. SIMPSON, Wyoming
JAMES ABDNOR, South Dakota
STEVE SYMMS, Idaho
GORDON J. HUMPHREY, New Hampshire
PETE V. DOMENICI, New Mexico
DAVE DURENBERGER, Minnesota

LLOYD BENTSEN, Texas
QUENTIN N. BURDICK, North Dakota
GARY HART, Colorado
DANIEL PATRICK MOYNIHAN, New York
GEORGE J. MITCHELL, Maine
MAX BAUCUS, Montana
FRANK R. LAUTENBERG, New Jersey

BAILEY GUARD, *Staff Director*
LEE O. FULLER, *Minority Staff Director*

SUBCOMMITTEE ON NUCLEAR REGULATION

ALAN K. SIMPSON, Wyoming, *Chairman*

PETE V. DOMENICI, New Mexico
STEVE SYMMS, Idaho

GARY HART, Colorado
DANIEL PATRICK MOYNIHAN, New York

CONTENTS

STATEMENTS

Tuesday, June 11, 1985

Page

Alvarez, Robert, Environmental Policy Institute, and Dr. Carl J. Johnson, radiation effects specialist, Denver, CO 138
  Prepared statement of Mr. Alvarez 144
  Prepared statement of Dr. Johnson 185
Mosteller, Dr. Frederick, chairman, department of health policy and management, Harvard University School of Public Health, and chairman, Oversight Committee on Radioepidemiological Tables; and Dr. Eugene Saenger, University of Cincinnati, OH, accompanied by Dr. Stephen Brown, staff officer for oversight committee 89
  Prepared statement of Dr. Mosteller 92
  Prepared statement of Dr. Saenger 107
Rall, Dr. Edward J., Deputy Director for Intramural Research, National Institutes of Health; Dr. Charles Land, Health Statistician, National Cancer Institute; Seymour Jablon, National Research Council; and Dr. Gilbert W. Beebe, National Cancer Institute 8
  Prepared statement of Dr. Rall 14
  Prepared statement of Mr. Jablon 46
  Prepared statement of Dr. Land 58
Young, Dr. Alvin L., senior policy analyst for life sciences, Office of Science and Technology Policy, Executive Office of the President, and chairman, Committee on Intragency Radiation Research and Policy Coordination 117
  Prepared statement 121

Wednesday, June 12, 1985

Boyer, Vincent, senior vice president, Philadelphia Electric Co., accompanied by Joyce P. Davis, General Physics Corp.; and Samuel T. Fife, chief union steward, Atomic Trades & Labor Council, Oak Ridge, TN 338
  Prepared statement of Mr. Boyer 341
  Prepared statement of Mr. Fife 358
Brown, E. Cooper, president, National Committee for Radiation Victims, and Kathleen M. Tucker, member, board of directors, National Committee for Radiation Victims, and president, Health and Energy Institute 257
  Prepared statement 264
Catlin, Robert, Electric Power Research Institute, Palo Alto, CA, and Dr. Ralph E. Lapp, consultant, Alexandria, VA 288
  Prepared statement of Mr. Catlin 292
  Prepared statement of Mr. Lapp 323
Fiksel, Dr. Joseph, manager, decision and risk management, Arthur D. Little, Massachusetts, and Richard Schmalz, counsel, American Nuclear Insurers 368
  Prepared statement of Dr. Fiksel 370
  Prepared statement of Mr. Schmalz 381
KMC, Inc., Donald F. Knuth, president, prepared statement 397
Tschaeche, A.N., certified health physicist, prepared statement 395
Willmore, Robert L., Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice 231
  Prepared statement 248
Yalow, Rosalyn S., prepared statement 409

ADDITIONAL MATERIAL

Questions and answers:

Page
- Responses of Dr. Rall to questions submitted by Senator Simpson ... 36
- Responses of Dr. Mosteller to questions submitted by:
  - Senator Kerry ... 97
  - Senator Simpson ... 100
  - Senator Grassley ... 105
- Responses of Dr. Young to questions submitted by Senator Simpson ... 128
- Responses of Mr. Alvarez to questions submitted by Senator Simpson ... 166
- Responses of Dr. Johnson to questions submitted by Senator Simpson ... 220
- Responses of Mr. Willmore to questions submitted by Senator Simpson ... 253
- Responses of Mr. Catlin to questions submitted by:
  - Senator Hatch ... 309
  - Senator Simpson ... 316
- Responses of Dr. Lapp to questions submitted by Senators Hatch and Simpson ... 327
- Responses of Mr. Boyer to questions submitted by:
  - Senator Hatch ... 347
  - Senator Simpson ... 350
- Responses of Mr. Fife to questions submitted by:
  - Senator Hatch ... 362
  - Senator Simpson ... 366
- Responses of Dr. Fiksel to questions submitted by Senator Hatch ... 375
- Responses of Mr. Schmalz to questions submitted by Senator Hatch ... 390

RADIOEPIDEMIOLOGICAL TABLES

TUESDAY, JUNE 11, 1985

U.S. Senate, Committee on Labor and Human Resources and the Subcommittee on Nuclear Regulation of the Committee on Environment and Public Works,

Washington, DC.

The committees convened in joint hearing, pursuant to notice, at 9:34 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin Hatch (chairman of the Committee on Labor and Human Resources) presiding, with Senator Alan K. Simpson, chairman, Subcommittee on Nuclear Regulation.

Present: Senators Hatch, Simpson, and Nickles.

OPENING STATEMENT OF SENATOR HATCH

The Chairman. I am especially pleased that Senator Simpson is cochairing these hearings with me, because since the fall of 1978, I have worked to understand the effects of more than 100 nuclear explosions in the Nevada desert, and to enact a fair remedy for the people whose cancers appeared in the wake of these nuclear tests.

It has been a long and, I have to admit, lonely struggle that seems to get lonelier every year. I welcome the company of someone who knows what it feels like. And of course, in the last two Congresses, Senator Simpson, as chairman of the Veterans' Committee, has pondered the effects of our nuclear testing upon veterans. Although he has moved on to become assistant majority leader, he gets no relief from the nuclear dilemma since he remains chairman of the Environment Committee's Subcommittee on Nuclear Regulation. So I sympathize with the Senator from Wyoming, and I am grateful that he will be here with us this morning.

These hearings today and tomorrow are devoted to the question of causality in radiation cancer cases. When a cancer victim claims that ionizing radiation caused his or her disease, how can we assess the merits of his or her claim, and how certain can we be of the judgments?

The question of causality should not be confused with the more common question of risk. Usually, people want to know how dangerous radiation is, how likely it is that a given dose of radiation will cause cancer. The same science addresses both causality and risk, but sometimes gives different answers to these questions.

The risk that a given dose of radiation will cause a cancer may be vanishingly small, yet if a person actually develops a cancer after this dose—especially a rare cancer—the likelihood that the radiation caused it can be quite substantial.

Generally, risk estimates pertain to safety standards, and causality assessments pertain to liability and justice. But because cancer terrifies people, the question of radiation cancer causality impacts every aspect of nuclear policy. Cancer afflicts one in three of us and will kill one in four of us. In every community, almost—really, in every family—one can see signs of a cancer epidemic. Therefore, the frequency with which radiation is blamed for this disease will greatly affect public perception of radiation dangers, and thus, public tolerance of nuclear technologies.

Unfortunately, causality is harder to judge than risk. The risks from various levels of radiation apply to whole populations and can be assessed by Federal agencies, but causality must be assessed case-by-case before courts and workers' compensation boards all over the country. Every cancer victim's situation is different. Each case requires a difficult individual evaluation.

Now, this predicament has provided a golden opportunity for so-called expert witnesses who represent the extremes of the nuclear debate. These would-be authorities have carried their ideological warfare, in my opinion, into the courtrooms, where judges and juries have been swayed this way and that, sometimes depending upon which expert put on the more razzle-dazzle performance. The rulings and the verdicts in these cases have been largely erratic. Neither justice nor public policy is served when the law is so capricious and liability is so unpredictable.

It is a hard reality of our times that only scientists truly comprehend the sciences upon which so many important decisions are grounded. This situation would be less troublesome if the scientists always agreed. But they do not. And what is worse, one can find an "expert," a Ph.D. or M.D., to attest to almost anything. In a country as big as ours, one can find at least a dozen.

Now, in light of this problem, the scientific community has two special responsibilities when its science is the crux of an important public debate. First, this scientific community should try to tell the rest of us about the science and its limits.

Second, this community should develop some guide for evaluating putative experts and their testimony.

Now, 2½ years ago, I proposed and Congress enacted section 7(b) of Public Law 97-414. This law was designed primarily to provide a guide for judging causality in radiation cancer cases, and an explanation of the science that laymen can grasp. The Department of Health and Human Services was required to develop the best estimates of likelihood that radiation-caused cancers for various cancer victims who had received various radiation doses. The Department was also obliged to discuss the science and its uncertainties.

This past fall, a panel of scientists completed the task at the National Institutes of Health. In January, the NIH published the resulting 355-page report, which is entitled, "Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables."

This morning, we shall discuss the science in the NIH report. And by the way, I didn't appoint these people. I just passed the law that allowed them to be appointed by, we hope, the top scientific minds in our country; and I believe that is so.

Does this report represent the best scientific expertise and data? Is the report congruent with the views of the mainstream scientific community? What does this report say about radiation cancer causality? How useful will this report be in assessing claims? How uncertain is the science involved here?

Tomorrow's hearing will dwell on the potential uses of the NIH report—should it be used in the courtroom and in other forums where radiation cancer liability is an issue? If so, how should this report be used in the courtrooms or other hearings?

Now, these hearings are not expected to resolve these issues. Rather, they are intended to initiate a focused debate within the scientific and legal communities. We must agree, it seems to me, on some means of providing perspective and regularity to evaluations of radiation cancer claims. It seems only reasonable to begin with a consideration of the NIH report, and a discussion of how well it might serve the purpose.

There is one thing that bothers me greatly about what I have been trying to do over the last number of years, almost 9 years, fighting for my folks out there in Utah, and of course, our neighbors in Arizona and Nevada.

I have one goal in mind, and that is to right the wrongs that were caused during those particular atmospheric tests; to right the wrong of the negligence of the Federal Government, which I think has been adequately proven by this committee and in courts of law.

I have not been interested, really, in the overall debate as to whether or not we should have nuclear power in America. But unfortunately, I really believe that my folks out in Utah are being used—used by extremes in the nuclear power debate, in such a way that they are going to wind up with nothing if we don't start waking up out there in Utah and Arizona and Nevada, and realizing that we are being used. We were used back in the fifties and sixties, and we are being used today by the ideologes in this field. And I am sick of it, and I am sick of being used myself as a U.S. Senator, too.

I have not seen anybody come up with any definitive answers here. I have not seen anybody come up with the ultimate way of resolving this. The attorneys themselves who are taking care of the suits—they do not want to resolve this legislatively unless it is a wide-open, "let's make the Federal taxpayers pay everything that we can prove in court or everything that we cannot prove in court; let's just make them pay" solution.

There is no reasonability about trying to resolve these problems, and frankly, I am getting kind of sick of it.

I think that I am going to come down very, very hard on those who use my people in Utah and our friends in our neighboring States. I think there have been tremendous wrongs here, and they have to be righted. I do not know if we can ever get that done, but we have come a long way. We have had major studies performed, and we are still doing studies out there in Utah. We passed legislation to create a radiation clinic; whether it will ever be funded or not depends upon the Appropriations Committee, but I suspect that it will be. And we now have legislation to create an environmental medical center at the University of Utah, which I also think will be useful, because it is the perfect place in the world to examine these environmental issues involving the life and health of our people.

I am concerned about these things, and I am concerned about doing justice here. I am not so concerned about ideology. I hope we can get out of the ideology and start talking science and start talking about what we do to create justice. If we do, I think we will go a long way.

I want to thank my dear colleague, Senator Simpson, for being willing to participate in these hearings and for the hard job that he has had and the excellent way that he has handled himself under the circumstances. We will turn to him at this time.

Senator SIMPSON. You are tired of it, eh?

The CHAIRMAN. I am tired of it.

Senator SIMPSON. I could tell that.

Orrin, I admire you greatly; I really do. I have watched you work, I have watched the fine work of your staff. You are an amazing gentleman, as you deal with so many things, and it is tough enough being chairman of this principal standing committee, but it is tougher when you get over into these areas filled with guilt and fear and emotion—and that is where you are, because I know—I chaired the Veterans' Affairs Committee and tried to deal with this one in many ways.

So, here we go, a subject of considerable controversy, the question of how best do we go about determining whether an individual who has suffered from cancer and who has at some earlier time been exposed to a known dose of radiation, and actually contracted cancer as a result of that—is that where we are? We know that it has occurred. Has the cancer, then, been a direct result of radiation exposure? Not only does that issue pose a tremendous and perhaps even unresolvable scientific dilemma; it also presents us with an imposing policy question: What approach should this Nation take, then, in compensating individuals who have contracted cancer, where the cause of the cancer is extremely difficult to pinpoint in the context of normal judicial tort principles. We still have things on the statute books called tort law in various States of the United States—cause, effect—those things are real.

In early 1983, we passed a law requiring the Department of Health and Human Services to come up with an approach, to estimate the likelihood that an individual who has a radiation-related cancer did, in fact, contract that cancer as a result of exposure to radiation. And that approach, now referred to, I guess, by the shorthand title of "probability of causation tables," is the subject of this extensive report which came to us in February and the subject of these next 2 days of hearings.

So the hearings that Senator Hatch and I have scheduled for today and tomorrow—and he has been a true leader in this area, and knows the personal frustration from representing constituents who are deeply affected. I do not have those, except the veterans constituency. I did have them for 4 years, and there are 28 million of them—I think I heard from every one of them during my tour of duty for 4 years. But here is what we have to focus on.

What, first, are the tables designed to do, and how were they prepared, and what are they designed to be used for. I hope we can find that. And, as part of that initial inquiry, we will be most interested in hearing the views of the various witnesses on the credibility, the validity, and the degree of certainty associated with those tables.

And second, we would wish to hear the views of the various witnesses on the numerous policy implications associated with the potential applications of those tables. I am fully aware of how this works, having served on and chaired the Veterans' Affairs Committee. It works out of boiling frustration, and the frustration is out there, and when the frustration appears, it almost reaches a point of, "Look, don't ask any questions anymore; just pay up; just forget the stuff and the hype and the hoohah. Just pay the bill." It is a nice idea, except that our Treasury will not quite take that kind of vigorous tapping in these days. I watched it with regard to presumptive diseases in the U.S. Code with regard to veterans. There are some 41 presumptive diseases, and they were put on the books because people got frustrated and said, "We are tired of having to try to prove this scientifically and medically, so we are going to make you feel guilty and raw and pay it." I have been there. Hodgkins disease is a presumptive disease under the U.S. Code if you have been in the U.S. armed services 7 years thereafter. Extraordinary. Go and look at the other 39 and 40. That is where we get. I watched it with agent orange, and through the good auspices of my friend, Alan Cranston, who is the ranking member of the Veterans' Affairs Committee, we pretty well put that one to bed. And it was raging in this country 2 years ago. Agent orange. "What are you going to do? What are you going to do?" And finally, we came up with a rather thoughtful approach which passed the Senate 95 to zip and went to the House and was approved there, and that is that you have to base it on sound medical and scientific information and evidence. Unless you do that, it cannot work.

So, that is what we have ahead of us. I thank you, Orrin, for inviting the Subcommittee on Nuclear Regulation to join with the Labor Committee in conducting the inquiry. And, as you and I have discussed on many occasions, the approach reflected in these tables, and indeed, we will find that, poses some tremendously difficult scientific and policy questions for those of us in Congress, and I look forward to working with you, Orrin, as we undertake these joint hearings. And I thank you very much.

The CHAIRMAN. Thank you, Senator Simpson.

[Opening statements of Senators Grassley and Dodd follow:]

OPENING STATEMENT OF SENATOR GRASSLEY

Senator GRASSLEY. Mr. Chairman, I am pleased to participate in this hearing this morning on radioepidemiological tables. I know that the problem of how to assess the effects of radiation on people has been of great interest to you, at least in part becasue of the nuclear testing in your neighboring State of Nevada. I know also that you and others are interested in the possible wider implications for the use of these tables, as indicated by the fact that this is a joint hearing and by the participation of Senator Simpson.

The completion of this report seems to me to be a big step forward in the understanding of the relationship between existing cancers and what may have caused them. The members of the ad hoc working group deserve our thanks for the work they have done, as do members of the National Academy of Sciences' oversight panel and the Federal Inter-Agency Review Group, both of which reviewed the work of the ad hoc working group.

It is probably important at this point to stress the many uncertainties inherent in this kind of effort, and to emphasize that we should use great caution in using these tables. I think several of our witnesses will stress that more work is necessary before we have a practical tool which we can use with confidence to isolate the contribution which radiation has made to the presence of a particular cancer in an individual. Beyond that, there is a large question as to how radioepidemiological tables might be used in court-adjudicated cases in which compensation is an issue.

Thank you, Mr. Chairman. I have nothing more and am looking forward to hearing the testimony of our witnesses.

OPENING STATEMENT OF SENATOR DODD

Senator Dodd. I would like to preface my remarks by thanking the distinguished chairman of the Labor and Human Resources Committee, Senator Hatch, for holding this 2-day series of hearings on the radioepidemiological tables prepared by the National Institutes of Health. These tables attempt to quantify the cause and effect relationship between specific doses of ionizing radiation and cancer production in humans, a process which could revolutionize the means through which our judicial system evaluates claims and awards compensation in radiation-related litigation. Without passing judgment on the results and ultimate application of their research efforts, I would also like to thank Dr. J. Edward Rall and the other members of NIH's ad hoc working group to develop radioepidemiological tables for the time and expertise which they devoted to this difficult analytical task. Last, I want to express my appreciation to Dr. C. Frederick Mosteller and the other members and staff of the National Research Council's Oversight Committee on Radioepidemiological Tables, whose review of the working group's assumptions, findings, and methodology was of invaluable assistance.

As I am sure these two distinguished groups of scientists would agree, the one sure thing we know about cancer is that it is the second leading cause of death in the United States. Beyond that, there exist a great many unanswered questions, particularly with respect to cancer-related etiology. For instance, while we do know that large doses of ionizing radiation can cause cancer in human beings, we cannot state with certainty whether or not the development of cancer in a specific individual was the result of radiation exposure. It is impossible to differentiate cancers induced by irradiation from those which occur "normally" in the population, and the relative influence of other "environmental" factors such as smoking habits, occupation, and lifestyle cannot be precisely quantified. All too often, this absence of a legally acceptable cause and effect relationship between radiation exposure and cancer development in individual cases results in conflicting and arbitrary court rulings which only add to the anguish of legitimately compensable radiation victims. For this reason, I believe that Congress and the scientific community have the duty and the obligation to help resolve the uncertainty surrounding this issue, in order to ensure that radiation victims and their families are treated fairly and uniformly under the law.

Because the establishment of a cause and effect relationship has proved to be problematic at best, some in Congress have proposed the development of a "probability of causation" compensation system. Under this system, an assessment would be made of the association between a specific radiation dose and an observed cancer. In order to determine the feasibility of this compensation mechanism, Congress through Public Law 97-414 directed the Secretary of Health and Human Services to "devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation-related cancers and who have received specific doses prior to the onset of such diseases developed cancer as a result of these doses." Under the act, the Secretary was also directed to assess the credibility, validity, and degree of certainty associated with these tables and to compile the formulas which yielded the probabilities of causation listed in them. It is now up to Congress, members of the scientific community, and others, to determine just how reliable and credible this data is.

Ultimately, NIH's radioepidemiological tables could be used to determine appropriate compensation for those exposed to radioactive fallout from U.S. nuclear weapons tests, those employed in uranium mines operated by the Federal Government, and service personnel who participated in U.S. nuclear weapons tests. In the private sector, these tables might potentially be applied ot occupational radiation exposure cases as well as to efforts to revise radiation protection standards for employees.

As we begin to consider this important issue, I hope the committee and eventually Congress as a whole will be able to debate the relative merits and inadequacies of the radioepidemiological tables. Indeed, there are legitimate questions concerning the adequacy of the data base and the methods and assumptions used in developing these tables. At the same time, I think we should keep in mind that the potential for expanded data bases and new research into radiation dosimetry and cancer incidence promise to greatly reduce the uncertainties associated with the radioepidemiological tables. Above, all, I think it is essential for us to consider the benefits and shortcomings of using the "probability of causation" compensation mechanism as an alternative to conventional judicial procedures.

The CHAIRMAN. We will turn to Senator Nickles at this time.

Senator NICKLES. Thank you, Mr. Chairman.

I do not have a statement except to compliment yourself and also Senator Simpson for your leadership in this area. We need your leadership—both of your leadership—in this difficult and hard-to-measure and calculate area. So I compliment you and look forward to today's hearings.

The CHAIRMAN. Thank you, Senator.

We will now turn to our panel.

It is my distinct pleasure to introduce the representatives of the Ad Hoc Group to Develop Radioepidemiological Tables, Dr. Edward Rall, Dr. Gilbert Beebe, Seymour Jablon, and Dr. Charles Land.

Welcome back. You have been before this committee before. We appreciate the work you have done. Your report is finally out—several hundred pages longer than I ever thought it would be. The country, it seems to me, owes you much for the diligence and industry with which you have tackled what really has been a set of perplexing problems. You have braved the controversy, and it seems to me you are about to brave some more, and it is good to have you here.

We are interested in taking your testimony at this time, and then we will have some questions for you.

Dr. Rall.

STATEMENT OF DR. J. EDWARD RALL, DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH; DR. CHARLES LAND, HEALTH STATISTICIAN, NATIONAL CANCER INSTITUTE; SEYMOUR JABLON, NATIONAL RESEARCH COUNCIL; AND DR. GILBERT W. BEEBE, NATIONAL CANCER INSTITUTE

Dr. RALL. Mr. Hatch, Mr. Simpson, members of the committee and subcommittee, I am pleased to have this opportunity to testify on the Department of Health and Human Services' response to section 7(b) of Public Law 97-414, the Orphan Drug Act.

The Secretary of HHS established the NIH ad hoc working group, of which I was chairman, to develop these tables mandated by this law, and these tables show the probability that certain cancers could result from prior exposure to radiation.

To aid the NIH working group and to review its work, the Assistant Secretary for Health asked the National Academy of Sciences to establish an oversight committee. Such a committee was formed and chaired by Dr. Frederick Mosteller. We should like to thank Dr. Mosteller and his oversight committee for their constructive criticism, which has been of great benefit.

In addition, the working group has had its various drafts reviewed by the Science Panel of the Committee on Interagency Radiation Research and Policy Coordination of the Office of Science and Technology Policy. The working group has also benefited by the groundwork laid by the National Council on Radiation Protection and Measurements, Committee No. 71.

Additionally, the National Academy of Sciences report on the effects on populations of exposure to low levels of ionizing radiation in 1980, the so-called BEIR-III report, was of great help.

The BEIR-III report was a synthesis of epidemiological data worldwide, and of 78 risk coefficients, we have used 40 from the BEIR-III report. However, 38 of the risk coefficients, we developed on the basis of more recent data. In addition, more recent data led to several changes from the BEIR assumptions. For example, we adopted a new wave-function time-response model for leukemia and bone cancer. The data supported that model better than any other.

We selected a constant relative risk time-response model for the other tumors. We added salivary gland as a radiogenic cancer, since there is now data to support that. We omitted lymphoma as a radiation-induced cancer, not seeing enough data to support that.

And finally, we avoided probability of causation calculations for certain cancers following exposure at younger ages because the data were too limited.

What is the probability of causation? Senator Hatch has given a very lucid explanation of it. Before I reaffirm what he said, let me just show you the types and sites of cancer that we decided on the basis of the best available evidence could be caused by prior exposure to radiation and for which there were enough data to permit risk estimates—figure 1.[1] First is leukemia, excepting chronic lymphatic leukemia, which does not appear to be caused by radiation insofar as we can tell. We list leukemia, type not specified, because sometimes, particularly in a deceased individual, no specific diagnosis may be available. We list leukemia separately from chronic granulocytic leukemia since these leukemias have different radiogenic characteristics.

Then, we have probability of causation tables for bone and joint cancer, but only caused by radium-224. We also have probability of causation tables for thyroid, breast, lung, esophagus, stomach, colon, liver, pancreas, kidney and bladder, and salivary gland.

In addition to having risk coefficients on the basis of data of individuals exposed to radiation who later developed cancer, we must have available a baseline risk of developing cancer. Fortunately, we had access to the National Cancer Institute SEER data, available through 1981. This is data on 10 percent of the U.S. population, and gives us our baseline risk.

The CHAIRMAN. Dr. Rall, have you made Xerox copies of these particular charts, so we can pass them out to the people who are interested here?

Dr. RALL. Yes; but they should be in the actual testimony.

The CHAIRMAN. Oh, they are in the actual text itself?

Dr. RALL. Yes.

Then we had to have some data on exposure to other carcinogens and unfortunately, the only data for which there are any quantitative estimates are on smoking, and we will discuss that later on.

Figure 2, shown by Dr. Beebe, who has been our efficient executive secretary since the group was established, is a definition of the probability of causation, and it is quite simply the excess risk which is the risk due to the radiation, divided by the baseline risk, plus the excess risk. And this shows why we need the SEER data to calculate the baseline risk. You can adjust the algebra and end up with PC equal to R over 1 plus R, where R is the excess risk over the baseline risk.

To reemphasize what you said, Senator, this is the probability that prior radiation caused cancer in someone who already has cancer. It is not the risk that with so much irradiation, you will then develop the cancer. There appear to be some individuals who seem to have missed that point, and I am glad you emphasized it so carefully.

A word about what radiation is. We are talking about ionizing radiation, where the radiation transfers energy to tissue by adding or subtracting electrons from atoms, which causes the atoms to ionize. These ions weaken or break chemical bonds in cellular DNA, and in general, experimental studies show that energy released in tissue by ionization is more likely to result in permanent effects such as cancer if the ionizations are clustered together in time and space—more so than if they are diffusely dispersed. And different types of radiation can be characterized in terms of the density of ionization along the radiation tracks. This is what is meant by linear energy transfer, or LET.

---

[1] Figures 1 through 8 referred to by Dr. Rall are attached to his prepared statement.

High-LET produced by neutrons or alpha particles from, say, radon, gives relatively few, fairly short tracks of dense ionization, which you can see in the lower circle in figure 3.

Any single ionization from high-LET radiation will tend to have many more close to it, and the likelihood of a permanent effect will simply be proportional to the number of ionizations, which is proportional, then, to the dose.

For low-LET radiation such as gamma or x ray, which is what we are mostly concerned with, the ionizations are rather sparsely distributed, and relatively many tracks are required to transfer a given amount of energy. Thus, clusters of ionization are more likely to occur when two tracks intersect than anywhere else along an individual track. The likelihood of a permanent effect is increased both by increasing the number of ionizations, which is proportional to the dose, and by increasing the number of intersections between the paths, which is proportional to the square of the dose.

These arguments lead to a linear dose-response relationship for the effects of high-LET radiation, in which the excess risk from a 10-rad dose, say, is one-tenth that from a 100-rad dose. I should note that one rad is defined as the deposition of 100 ergs of energy in one gram of material, or tissue.

They also lead to a linear-quadratic dose-response relationship for low-LET radiation, in which the risk from 10 rads is somewhat less than one-tenth that from 100 rads. The 1980 BEIR Committee considered that the most likely relationship for most cancers resulting from low-LET radiation was one in which the risk was proportional to the dose plus the dose-squared over 116, the so-called linear-quadratic. Here, the risk from 10 rads is approximately one-seventeenth that from 100 rads.

The working group adopted the BEIR model for low-LET radiation for all sites except thyroid and female breast, because with those two sites, the epidemiologic data suggest a linear dose-response relationship. Figure 4 shows the difference between the excess risk to be expected from a given radiation dose if the form of the dose relationship is linear, versus that when it is the linear-quadratic formulation.

Experimental studies also demonstrate that the body's natural repair mechanisms can erase much ionization damage within a few hours. This consideration has little to do with the effectiveness of high-LET radiation, but separation in time of two intersection tracks of low-LET radiation reduces the chance that permanent effects may result from the interaction of ionizations from them.

The practical effect of this is that two radiation doses, whether high- or low-LET, can be treated independently if they are separated in time by more than a few hours. Thus, the excess risk from two 100-rad doses of low-LET radiation received on different days is twice the risk from a single 100-rad dose—which I should point out is less than the risk from a single 200-rad dose.

Figure 5 shows the dose-response relationships we have used. For low-LET radiation it is linear for breast and thyroid, linear-quadratic for other solid tumors and leukemia. For high-LET radiation, the only ones we have calculated are for bone and lung, and there it is linear.

Another and different question is how that risk is distributed over time. In reports like that of the 1980 BEIR Committee, this question was important mainly because no major irradiated population had been followed until the end of life, and in order to estimate lifetime risk and data as it pertained to, say, only 30 years of exposure, it is necessary to know whether the excess risk is increasing, decreasing, or remains about the same toward the end of observation.

Lifetime estimate is a rather abstract concept, and rough estimates may be acceptable for some purposes. The BEIR Committee coped with the problem by assuming that after 30 years, there was essentially no remaining excess risk for leukemia or bone cancer, and for other cancer sites, the committee gave alternate estimates of lifetime risk.

One estimate was that the excess risk after 30 years of exposure was the same as that observed during years 11 to 30. The second estimate was based on the assumption that excess risk increases or decreases over time, as the exposed person gets older, in direct proportion to the risk that would be expected in the absence of exposure. This is important because in general, the risk of cancer increases as a function of age.

Figure 6 demonstrates the difference between these two methods. The absolute risk time projection model in the upper part of the figure shows that the risk due to radiation is always a constant number greater than the spontaneous risk at all points after the latent period. The lower curve shows an estimate of the relative risk time projection model in which the solid line, the radiogenic risk, is a constant proportion of the baseline risk.

It is important to note that the absolute number of cases of cancer will be the same in either of these models. The difference will be in the extrapolation beyond the period of observation.

Fortunately, in the time since the BEIR–III report, more data have become available which strongly support the relative risk time projection model for most tumors. However, this is not true for all tumors. Recent data on bone cancer in a group of German patients given radium-224 and more data on radiation-induced leukemia permit formulation of a wave-like temporal distribution of risk which much more accurately describes the observations. Figure 7 shows the results we have calculated using the empirical data on leukemia, both from the ankylosing spondylitis study and from the Japanese study. This figure shows the radiogenic risk of developing acute leukemia after exposure to a given amount of radiation. You will note several things: One, this appears to be wave-like, and two, it is highly dependent on the age of the individual at the time of exposure, so that the younger individuals are considerably more sensitive and show a much more rapid increase in risk.

For other cancers, the excess risk seems quite clearly to be proportionate to the age-specific baseline risk.

The CHAIRMAN. Doctor, it seems to me if you look at that graph, the younger the age, the more it matters. Am I interpreting that correctly?

Dr. RALL. Yes; that is quite true.

The CHAIRMAN. So that is why our people in Utah are so upset, because they seem to have this high incidence of leukemia among children. Your chart seems to show that very strongly.

Dr. RALL. Yes. The data seem to show that, and only recently have there been enough data to show that groups exposed at older ages have an increased risk from radiation.

Dr. Beebe draws my attention to the fact that these curves are normalized for risk so they do not give you the absolute magnitude of the risk; they give you the shape of the curve. Although the risk from radiation is highest in children, the PC does not necessarily follow the risk from radiation since the normal risk for leukemia varies a great deal with age.

The CHAIRMAN. Well, it has the greatest impact during the youthful years.

Dr. RALL. That is right.

One of the problems that we considered was that the BEIR Committee had assumed for all the cancers other than leukemia that the risk began 11 years after exposure, and there was no risk prior to that time. Unfortunately, there are not very good data available between 5 and 10 years, but biological functions are generally not what are called step functions, where they are zero until a certain time, and then all of a sudden jump up to a high value. So we have arbitrarily used a smoothing function to go from 5 to 10 years. Figure 8 shows what this function is, and how to break it down into yearly intervals for calculation.

I should say a word before we go on about high-LET radiation, which includes radon, alpha particles from radon, neutrons, et cetera. Right now, the National Academy of Science has established a committee to investigate exactly how effective high-LET radiation is in causing cancer. It is clearly more effective than low-LET radiation. The problem is exactly how much more effective is it, particularly when one is dealing with problems such as the energy of the neutrons or the kinds of the alpha particles.

At this present time, we decided that the data are not adequate for us to make accurate estimates of the relative carcinogenicity of high-LET radiation. So the tables we have presented are not applicable to high-LET radiation, with two exceptions. These are bone cancer, as I have previously mentioned, occurring after the injection of radium-224, and lung cancer after exposure to radon. For both of these, there are good data available to make risk estimates.

In addition to the tables, the report contains a more detailed analysis of the points I have just made, with background material on cancer and radiation carcinogenesis and it describes in some detail how the probability of causation can be calculated in any particular case. The graphs and tables are presented for each cancer that can be caused by radiation and for which quantitative risk estimates are available; the problems associated with that cancer, and all of the material necessary for an analysis of the probability of causation.

This has given rise to some redundancy, but we thought it important that all the material for each cancer be developed in one place.

The CHAIRMAN. Dr. Rall, let me interrupt you at this point.

Senator Simpson has a leadership meeting that begins at 10:30. If you don't mind, I would like to put your complete statement in the record, and I would like to allow him some time to ask you some questions that are on his mind at this particular point, and then maybe I will have some questions.

It is extremely interesting to me. I have been picking up more since you have been explaining it than I did by reading the report.

But let us turn to Senator Simpson at this time and let him get some questions in.

[The prepared statement of Dr. Rall and responses to questions submitted by Senator Simpson follow:]

FOR RELEASE UPON
DELIVERY

STATEMENT OF

J. E. RALL, M.D., Ph.D.
DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH

NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
AND THE ENVIRONMENT AND PUBLIC WORKS SUBCOMMITTEE ON NUCLEAR REGULATION

UNITED STATES SENATE

JUNE 11, 1985

Mr. Hatch, Mr. Simpson, and members of the committee and the subcommittee:

I am pleased to have this opportunity to testify on the Department of Health and Human Services' response to Section 7(b) of Public Law 97-414, the Orphan Drug Act. The Secretary of HHS established the NIH Ad Hoc Working Group, of which I was Chairman, to develop the Radioepidemiologic Tables mandated by this law, which were submitted to Congress in January, 1985. These tables show the probability that certain cancers could result from prior exposure to radiation.

To aid the NIH Working Group and review its work, the Assistant Secretary for Health asked the National Academy of Sciences to establish an Oversight Committee. Such a committee was formed and chaired by Dr. C. Frederick Mosteller. The Working Group would like to thank Dr. Mosteller and the Oversight Committee for their constructive criticisms, which have been of great benefit. In addition, the Working Group has had its various drafts reviewed by the science panel of the Committee on Interagency Radiation Research and Policy Coordination of the Office of Science and Technology Policy, Executive Office of the President. The Working Group has also benefited by the groundwork laid by the National Council on Radiation Protection and Measurements, Committee No. 71, which already was addressing the question of probability of causation. Additionally, the National Academy of Sciences report on the Effects in Populations of Exposure to Low Levels of Ionizing Radiation: 1980 (BEIR III) was of great help to the Ad Hoc Working Group. However, since most of the material on which that report was based had been published in 1979 or earlier, we have, in many instances, used more recent data. For example, although 40 of some 78 risk coefficients that we used in our report were derived from BEIR III, 38 were values recalculated on the basis of newer data. We made several other significant changes from BEIR III, including: adoption of a new wave-function time-response model for leukemia and bone cancer; selection of the constant relative risk time-response model for other tumors; addition of cancer of the salivary gland as a radiogenic cancer and omission of lymphoma as a radiation-induced cancer. Finally, we avoided probability of causation calculations for certain cancers following exposure at younger ages because the data were too limited.

Probability of Causation

What is the probability of causation? Under Public Law 97-414, section 7(b)(1) the Secretary of Health and Human Services is required to "devise and publish radioepidemiologic tables that estimate the likelihood that persons who have or have had any of the radiation-related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses." Given that a specific cancer has occurred in a person of specific demographic and perhaps other characteristics, the chance that it might have occurred is the sum of two separate risks: (1) the normal baseline risk for a person of those specific demographic and perhaps other characteristics to develop the cancer in question; and (2) the radiogenic risk for the particular antecedent exposure of individuals of the same demographic and perhaps other characteristics to cause the specified cancer. Then the probability of causation (PC) is the ratio of the radiogenic risk to the total risk. That is,

$$PC = \frac{\text{Radiogenic risk}}{\text{Baseline risk + Radiogenic risk}}$$

Note that the calculation applies to people who *already have cancer*. It does not represent the likelihood that cancer may occur some time in the future.

Source of Data

I will now discuss what data the Working Group decided were most appropriate for the report. We concluded that, in general, and particularly for the calculation of specific probabilities of causation, we should use the epidemiologic data on humans exposed to radiation. However, we also looked to the available animal data and *in vitro* data for a better understanding of the mechanism of radiation carcinogenesis and for mathematical models of the relationships between radiation exposure, time after exposure, and diagnosis of cancer. In general, the quantitative data were derived exclusively from human epidemiologic data, but some of the qualitative aspects of the models have their background in animal experimentation.

Dosage of Radiation and Risk

The Working Group spent a great deal of time developing methods for evaluating the effects of low doses of radiation, and of higher doses received in small fractions spread out over time. This is a subject to which epidemiological studies have contributed relatively little, but on which experimental studies have been especially informative. Ionizing radiation transfers energy to tissue by adding or subtracting electrons from atoms, a process called ionization.

Ionization can weaken or break chemical bonds in cellular DNA. The results of experimental studies indicate that, in general, energy released in tissue by ionization is more likely to result in permanent effects, like cancer, if the ionizations tend to be clustered together in time and space than if they tend to be dispersed. Different types of radiation can be characterized in terms of the density of ionizations along the radiation tracks (the paths that that particular radiation travels); this is what is meant by linear energy transfer, or LET. High-LET radiation, e.g., neutrons or alpha particles, tends to produce relatively few, fairly short, tracks of dense ionization. Thus any single ionization from high-LET radiation will tend to have many more close to it, and the likelihood of a permanent effect is simply proportional to the number of ionizations, i.e., proportional to dose. For low-LET radiation, e.g., gamma ray or X ray, ionizations tend to be more sparsely dispersed along radiation tracks, and relatively many tracks are required to transfer a given amount of energy. Thus clusters of ionizations are more likely to occur where two tracks intersect than elsewhere along a track. The likelihood of a permanent effect is increased both by increasing the number of ionizations, which is proportional to dose, and by increasing the number of intersections between pairs of tracks, which is proportional to the square of dose.

The above arguments lead to a linear dose-response relationship for effects of high-LET radiation, in which the excess risk from a 10-rad dose (say) is 1/10 that from a 100-rad dose. One rad is defined as the deposition of 100 ergs of energy in one gram of material. They also lead to so-called linear-quadratic dose-response relationships for low-LET radiation, in which the risk from 10 rad is somewhat less than 1/10 that from 100 rad. The 1980 BEIR Committee considered that the most likely relationship for most cancers resulting from low-LET radiation was one in which risk was proportional to

dose + (dose-squared)/116.

Here, the risk from 10 rad is 1/17 that from 100 rad.

The Working Group adopted the BEIR model for low-LET radiation for all sites except the thyroid gland and the female breast, for which epidemiological data suggest a linear dose-response relationship.

Experimental studies also demonstrate that the body's natural repair mechanisms can erase much ionization damage within a few hours. This consideration has little to do with the effectiveness of high-LET radiation, but separation in time of two intersecting tracks of low-LET radiation can reduce the chance that permanent effects may result from the interaction of ionizations from them. The practical effect is that two radiation doses, whether high- or low-LET, can be treated independently if they are separated in time by more than a few hours. Thus the excess risk from two 100-rad doses of low-LET radiation received on different days is twice the risk from a single 100-rad dose, which is less than the risk from a single 200-rad dose:

2 x (100 + (100-squared)/116) = 372 < 545 = 200 + (200-squared)/116.

Similarly, the risk from a 50-day continuous exposure to low-LET radiation at the rate of one rad per day is no greater than 50 times the risk from a single 1-rad exposure, and much less than the risk from 50 rad received in a single day.

As a practical matter, it makes little difference whether a small dose, e.g., one of 5 rad or less, is subdivided or not; thus, in the above example, the risk from a 50-rad dose spread out over 50 days is nearly the same as the sum of risks for 10 separate 5-rad doses.

Distribution of Risk Over Time

Another and different question is how that excess risk is distributed over time. In other reports, like that of the 1980 BEIR committee, this question was important mainly because no major irradiated population has yet been followed until the end of life, and in order to estimate lifetime risk from data that pertain to, say, the first 30 years after exposure, it is necessary to know whether the excess risk was increasing, decreasing, or remaining about the same toward the end of that period of observation. Lifetime risk is a rather abstract concept, and rough estimates may be acceptable for many purposes. The BEIR committee coped with the problem by assuming, on rather good evidence, that after 30 years there was essentially no remaining excess risk of leukemia or bone cancer. For other cancer sites, the committee gave alternative estimates of lifetime risk. The first was based on the assumption that the average yearly excess risk beyond 30 years after exposure was the same as that observed during years 11-30, that is, after a minimal latent period of 10 years in which there was essentially no risk. The second estimate was based on the assumption that excess risk increases or decreases over time, as the exposed person gets older, in direct proportion to the risk that would be expected in the absence of exposure. The second estimate was higher than the first, because cancer rates in general increase with age.

The time-distribution requirements of the present tables are much more stringent, because the calculation of a PC concerns risk, not over a lifetime or a 30-year interval, but at a specific time after exposure, namely, the diagnosis date of a particular cancer. Fortunately, epidemiological research subsequent to the BEIR report provided the Working Group with a more nearly adequate basis for estimating time to response. For example, recent data on bone cancer risk in a group of German patients given therapeutic injections of a short-lived isotope of radium allowed precise estimation of a wave-like temporal distribution of risk. In fact, bone cancer following injection of Ra-224 is unlikely to be an important application of the tables, but because of striking similarities to observations of leukemia risk, the Working Group was able to fit a similar model to data for the main type of radiation-related chronic leukemia, and a somewhat more complicated model for acute leukemia. We believe that these models provide a significant improvement over previous estimates, in that they permit quantification of the frequent observation that radiation-induced leukemia tends to occur fairly soon after exposure.

For other cancers associated with radiation exposure, recent epidemiological data support the second of the alternative models used by the BEIR committee, in which excess risk increases or decreases over time following exposure, as the exposed individual gets older, in direct proportion to age-specific baseline cancer rates. This model allows a particularly simple tabulation of coefficients for PC calculation, but the Working Group chose it because of strong evidence favoring it over other models, like the first BEIR alternative or the wave-like models corresponding to leukemia and bone cancer.

Unlike the wave-like models used for leukemia and bone cancer, the constant relative risk model used for other cancers is rather vague on when the excess risk begins. The Working Group agreed generally with the conclusion of the BEIR committee that it takes at least 10 years before the excess risk reaches its full value relative to baseline risk, but felt that the PC calculations required a smooth transition from a zero excess immediately after exposure to the full value after 10 years.

There is a problem with respect to the relative carcinogenicity of high-LET radiation, of which I spoke a moment ago. Many kinds of high-LET radiation appear to be more effective in causing cancers than low-LET radiation. Several committees are currently investigating the extent to which high-LET radiation is more carcinogenic than low-LET radiation. Suffice it to say that, in most instances, the data are inadequate for us to make accurate estimates of the relative carcinogenicity of high-LET radiation; hence the tables we have developed are not applicable to high-LET radiation, with two exceptions. These are bone cancer developing after injection of radium 224, and lung cancer after exposure to radon, for both of which good human epidemiologic data are available. For these cancers, probability of causation is tabulated for high-LET radiation.

The report on the Radioepidemiologic Tables includes, in addition to tables, a more detailed analysis of the points I have just made. It contains background material on cancer and carcinogenesis, with particular attention to radiation carcinogenesis. It also describes in some detail how the probabilities of causation have been calculated. Graphs and tables of the probability of causation are presented for each cancer that can be caused by radiation and for which quantitative risk estimates exist; the problems associated with that cancer are discussed, and basically all the material necessary for an analysis of the probability of causation is provided. This has given rise to some redundancy, but we thought it important that all the material for each cancer be developed in one place.

Two special points should be made. One is the exact method by which the calculations were done and an explanation of how anyone can make calculations using the material we have developed. I shall ask Charles Land, who was responsible for a great deal of this work, to tell you in more detail how the probabilities can be calculated. The second point is that the group has been enjoined by numerous advisers to attempt some quantitative estimate of the uncertainties surrounding these calculations. Seymour Jablon has devoted considerable attention to this, and Chapter VII of the report gives an analysis and estimates for the uncertainties for each cancer as a function of several variables. Following Dr. Land's presentation, I should like Mr. Jablon to tell you how this analysis has been done and what the results show.

This concludes my prepared statement. If there are any questions, I would be pleased to answer them.

FIGURE 1

TYPES & SITES OF CANCER

- Leukemia, except CLL
- Leukemia, acute forms
- Leukemia, CGL
- Bone & Joint (Ra-224)
- Thyroid
- Breast
- Lung
- Esophagus
- Stomach
- Colon
- Liver
- Pancreas
- Kidney & Bladder
- Salivary Gland

FIGURE 2

DEFINITIONS

$$PC = \frac{\text{Excess (Radiogenic) Risk}}{\text{Baseline Risk} + \text{Excess Risk}}$$

$$\text{Define } R = \frac{\text{Excess Risk}}{\text{Baseline Risk}}$$

$$\text{Then } PC = R/(1+R)$$

FIGURE 3

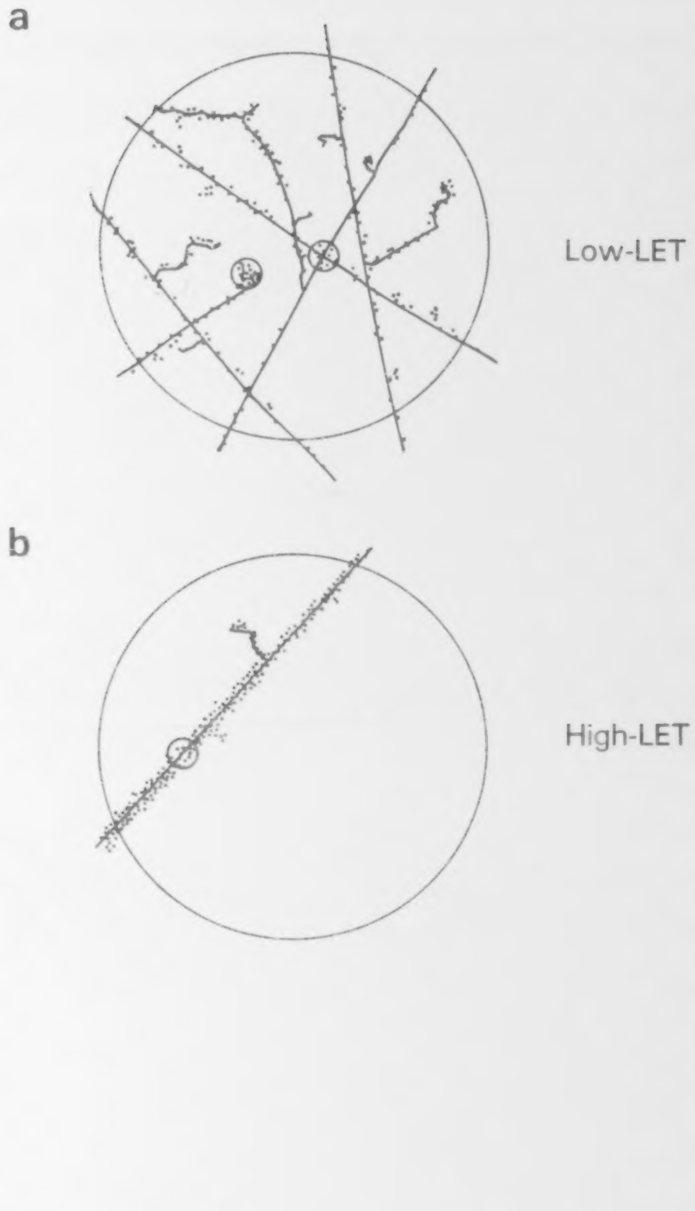

a
Low-LET
b
High-LET

FIGURE 4

COMPARISON OF LINEAR AND LINEAR-QUADRATIC (BEIR III) MODELS FOR EXCESS CANCER AS A FUNCTION OF RADIATION DOSE

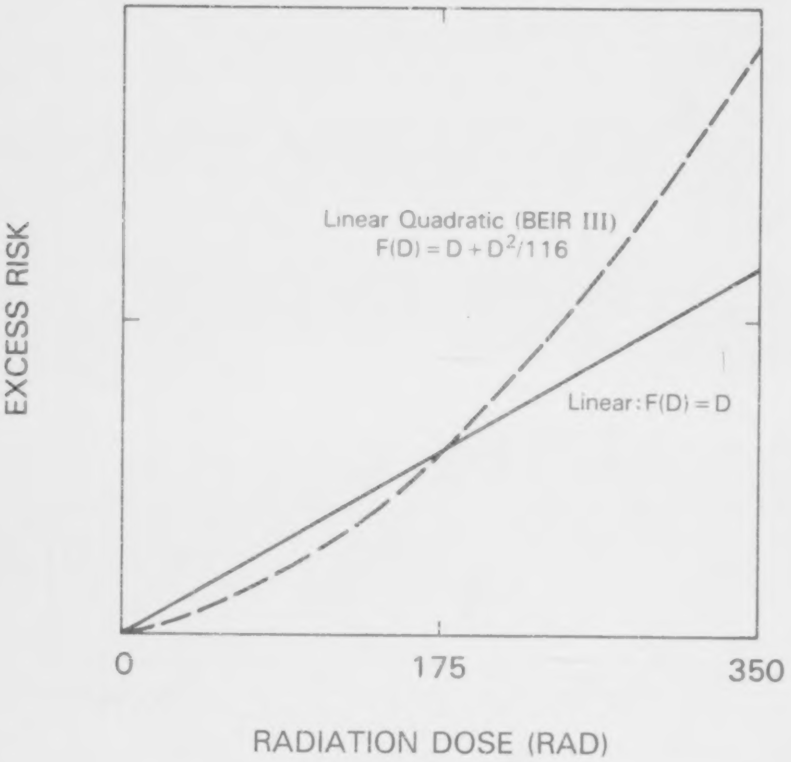


FIGURE 5

DOSE RESPONSE

Low-LET

Linear: breast & thyroid

LQ: other solid & leukemia

High-LET

Linear: bone & lung only

FIGURE 6

COMPARISON OF ABSOLUTE AND RELATIVE RISK MODELS

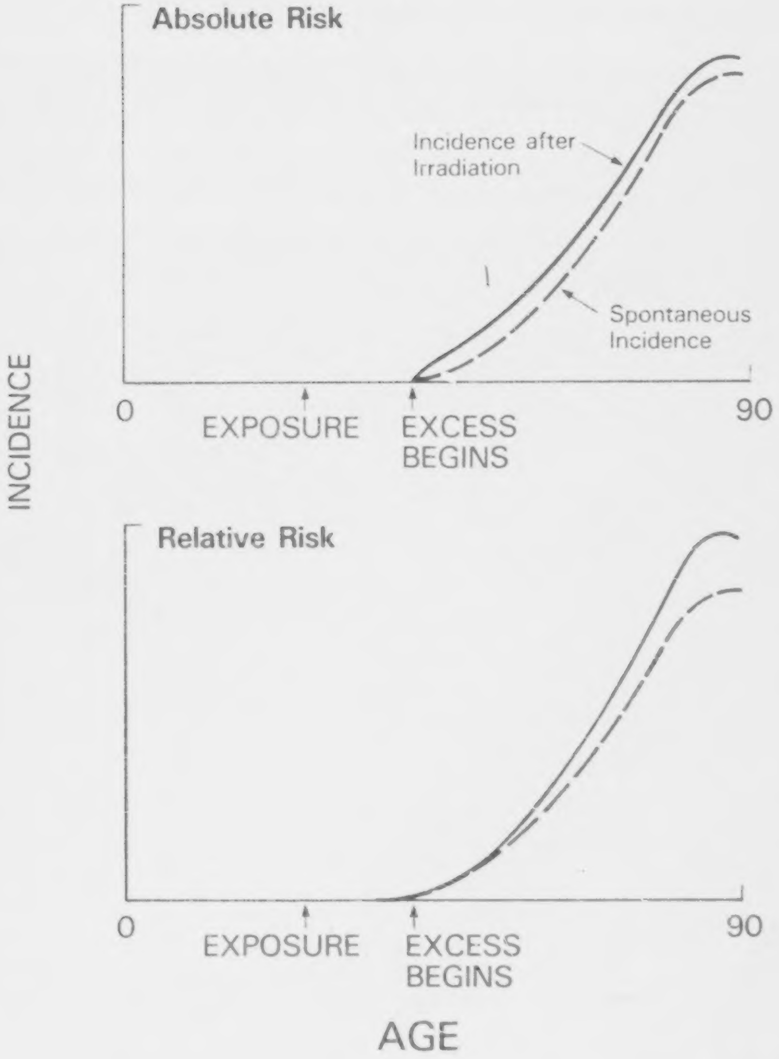
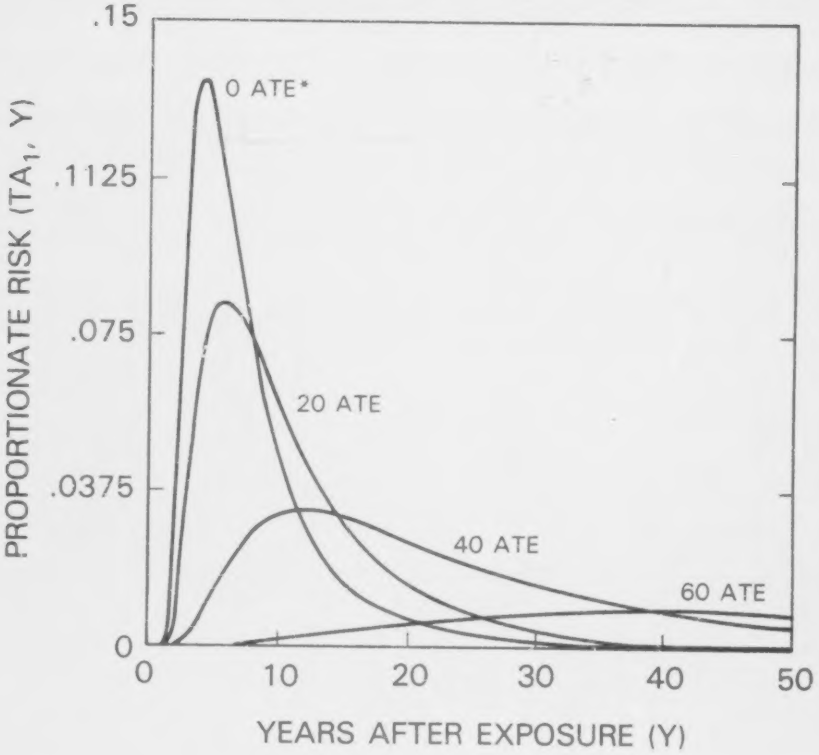


FIGURE 7

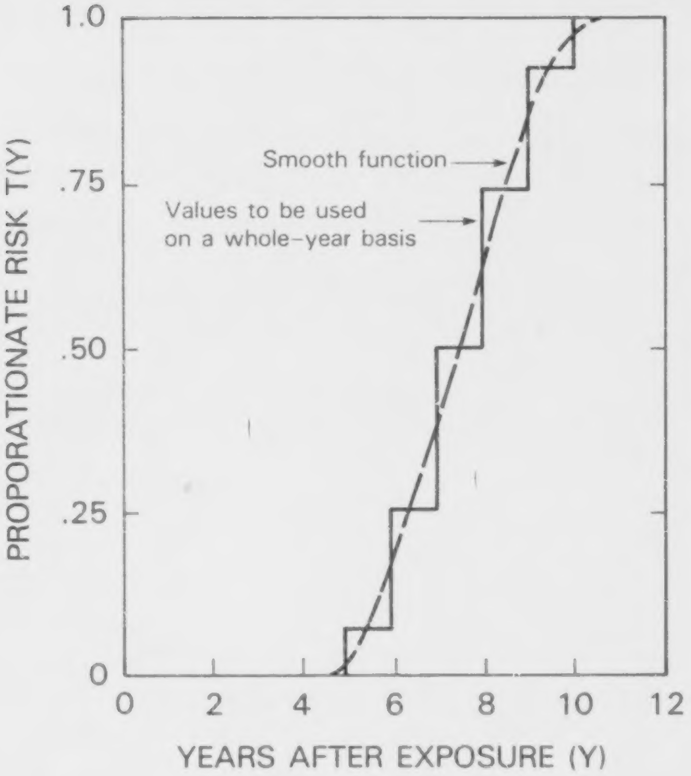
TIME TO TUMOR MODEL ACUTE LEUKEMIA



*Age at exposure (A_1)

FIGURE 8

TIME TO TUMOR MODEL SOLID TUMORS (Ex. bone)



RISK COEFFICIENTS

NAS BEIR III (1980 synthesis of epidemiologic data) — major source

1984 data used for lung, breast, thyroid, and salivary gland

BASELINE RISK

Source: NCI SEER* Data, '73-'81

Host characteristics at diagnosis
  Demographics

  Exposure to other carcinogens:
    smoking . . .

---

*Cancer Surveillance, Epidemiology, and End-Results reporting program

DOSE RATE

- Fractionated or continuous exposure under 5 rad, or over 5 rad if received within 24 hr., treated as single dose

- Otherwise, each fraction treated separately

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD

FOR DR. EDWARD RALL

1. In your report, you have addressed the various uncertainties associated with the "probability of causation" methodology, and identified those areas where further scientific work is necessary. After reviewing the report, it appears that, in some respects, these uncertainties are rather large. Do we know enough, at this stage, to use this approach as a basis for compensating individual cancer claimants, or would we be better off if we addressed these scientific uncertainties with greater precision?

2. In the report of the National Research Council Oversight Committee, it was noted that the ongoing dose reassessment work for the Hiroshima and Nagasaki populations could result in marked changes in the estimates in these tables and, as a result, "seriously affect the amount of compensation that might be awarded a claimant." How significant a factor is this dose reassessment effort, in your view, in reaching the probabilities set forth in this report, and how much additional precision would we have after completion of the dose reassessment work?

3. Please discuss briefly the range of uncertainties in these tables in the context of three individual cases. Suppose, for example, that three individuals developed leukemia and that, based upon the individual circumstances in each case, one person's "PC" was 5%, one's was 30%, and one was 50%. For each of these three cases, what is the range of uncertainty in these estimates?

4. What are the potential impacts of this entire methodology on the way in which we establish radiation protection standards, and what impact will there be, in your judgment, if we establish a system to compensate individuals in one context where, in a different context, an exposure of the same amount is within federally-permitted limits?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205
Building : 1
Room : 122
(301) 496- 1921

DR. J. E. RALL'S ANSWERS TO SENATOR ALAN K. SIMPSON'S QUESTIONS

1. Q. In your report, you have addressed the various uncertainties associated with the "probability of causation" methodology, and identified those areas where further scientific work is necessary. Do we know enough, at this stage, to use this approach as a basis for compensating individual cancer claimants, or would we be better off if we addressed these scientific uncertainties with greater precision?

A. The present tables should be useful aids in determination of compensation for individuals if their probability of causation is found to be relatively high--perhaps over 50%. Furthermore, if the probability of causation is calculated to be, say, 5% or less, this would be an important consideration in a compensation case. Obviously, it is a Congressional decision what do with the number of cases that fall in the middle. The second part of your question asks whether we would be better off if we address the uncertainties with greater precision. Certainly we would be. I suspect, however, that it is not possible to address the uncertainties with any greater precision at this time. Although in a few years the Japanese dose reassessments will be available and we will have a longer follow-up on radiated individuals, there is nothing that can be done to accelerate that process. Furthermore, there is no reason at this time to think these changes are going to be large ones. It certainly seems highly improbable that any individual who would have a probability of causation of, say, 2%, as presently calculated, would go above 15% when the new data are available.

2. Q. In the report of the National Research Council Oversight Committee, it was noted that the ongoing dose reassessment work for the Hiroshima and Nagasaki populations could result in marked changes in the estimates in these tables and, as a result, "seriously affect the amount of compensation that might be awarded a claimant." How significant a factor is this dose reassessment effort, in your view, in reaching the probabilities set forth in this report, and how much additional precision would we have after completion of the dose reassessment work?

A. There is reason to think that the dose reassessment will probably increase the radiation risk for cancers by something between 50% and 100%. However, because of the way the probability of causation is calculated, this will not necessarily increase the probability of causation by as much as a factor of 2. Another totally unknown factor is what happens to the risks of cancer at longer periods of time after radiation. We have used the relative risk method of extrapolating these figures, and for the data presently available this approach is quite satisfactory. However, it may be that some of the other cancers will resemble leukemia and the risk of cancer will, in point of fact, fall 30 or 35 years after the radiation. If this were to happen, then the probability of causation, under certain circumstances, would decrease. At present, this is, of course, a complete unknown.

3. Q. Please discuss briefly the range of uncertainties in these tables in the context of three individual cases. Suppose, for example, that three individuals developed leukemia and that, based upon the individual circumstances in each case, one person's "PC" was 5%, one's was 30% and one was 50%. For each of these three cases, what is the range of uncertainty in these estimates?

A. The table below gives what we consider to be the 90% credibility levels for individuals who develop leukemia, type unspecified (but not chronic lymphatic leukemia), for the calculated PCs of 5%, 30% and 50%. These figures are derived from Table VII-8 on page 113 of our report, for all leukemias, and entered in to Table VII-9 on page 114. However, the upper bound of the 50% PC has to be calculated from equation 1 on page 97. I think this table demonstrates that relatively low PCs have a very low chance of being high, and relatively high PCs are most unlikely to be low, whereas intermediate values can be on the low side or on the high side.

	90% Credibility Limits	
Calculated PC	Low	High
5%	4%	15%
30%	25%	59%
50%	43%	78%

4. Q. What are the potential impacts of this entire methodology on the way in which we establish radiation protection standards, and what impact will there be, in your judgment, if we establish a system to compensate individuals in one context where, in a different context, an exposure of the same amount is within federally-permitted limits?

A. This is indeed a vexing question. I suppose it can be restated by asking how a government can be considered rational when it permits exposure to levels of radiation such that an individual thus exposed who later develops a cancer may have a probability of causation calculated at a level for which he should be compensated. The Government seems to be speaking with two voices, but this perhaps is not necessarily the case, if one looks at most hazardous occupations. I think, for example, of steel workers on sky scrapers, or coal miners, and compare them with those in relatively mundane occupations, such as clerical workers. In all occupations there is a certain possibility of danger or loss of life or limb; in the case of radiation, the risk is for cancer. These risks are generally accepted as being occupational risks, the courts accept liability claims and the Congress has allowed for them by, among other things, workmen's compensation and a variety of insurance schemes. However, it is possible that these tables may give industries both an incentive to lower the amount of radiation to which workers are exposed and also some way of calculating, knowing the incidence of each of the radiogenic cancers, how many claims they might have to pay, rather than depending upon what have, so far, been somewhat capricious determinations by judges and juries.

J. E. Rall, M.D., Ph.D.
Deputy Director for
Intramural Research

July 30, 1985

Senator SIMPSON. Orrin, thank you very much, and thank you, Dr. Rall. I appreciate that, and you are kind to accommodate me.

I am just thinking how I would feel if I were a juror, listening to that. I would need to bone up a bit, I think, I really do think I would, and that's what makes it tough, because somewhere along the line when you do compensate human beings for error in the civil field—we are not talking about criminal activity—you have to come back to tort law. And when you get to tort law, you get to frustration; and when you get to frustration, you get to presumptive diseases and probabilistic approaches. And I am not saying I am opposed to that. I am just saying that it is extremely difficult.

Let me ask you—your group has been criticized by some, including the National Committee for Radiation Victims, as having—I believe their phrase was "biased attitudes" about the health risks of radiation. Beyond that, the charge is also sometimes made, without questioning your professional capabilities, all of you, which are extraordinary—that nevertheless, those professional careers are in a sense beholden to the—this is the comment of criticism—beholden to the nuclear industry and Federal agencies such as the Department of Energy and the Veterans' Administration, and as a result, your report is unfairly minimizing the consequences of radiation exposure. Would you please share with me your response to that critism?

Dr. RALL. One criticism is ad hominem and one is more or less scientific. The ad hominem argument is answered by the fact that as far as I know, none of us is indebted to the Department of Energy for support of our research with the exception of Mr. Jablon, working with the National Academy of Sciences, which accepts Department of Energy support.

Scientifically, it seems to me, we have done our best to wade through the data that are available, and we would welcome precise comments as to where anyone thinks we erred in choosing data or in developing mathematical models. The data we have used are all in the open literature, and we have attempted as carefully as we can, given a wide range of uncertainties, to make the best calculations we can.

Senator SIMPSON. In your report, do you address the various uncertainties that are associated with this probability of causation methodology? And you identifed those areas where further scientific work is necessary. That was of interest. And after reviewing the report, it appears that in some respects, these uncertainties are very large, as I would assess it. Do we know enough, then, at this stage to use this approach as a basis for compensating individual cancer claimants, or would we be better served or better off if we addressed these scientific uncertainties with ever greater precision?

Dr. RALL. We will clearly be better off if we address these uncertainties as quantitatively as possible. I gather that the problem that confronting the Congress is that something that should be done relatively soon at a time when we cannot completely resolve these uncertainties. In 2 or 3 years, with the dose recalculations on the Japanese data and a longer followup, some improvement will be possible.

The uncertainties for any given cancer depend in large part on two variables. One is the cancer involved. For leukemia and for breast cancer the risk coefficients are reasonably good. For other cancers, they are not nearly as firm and some are better than others.

The other uncertainty depends on the calculated value of the probability of causation. If you have a probability of causation that calculates out to be, say, 80 percent, the odd in most instances particularly with leukemia, are quite remote that it will be below 50 percent.

Furthermore, if the probability of causation calculates to be 5 percent, the chances that the probability will really be more than 15 percent is again rather remote.

So that at the extremes, the probability of causation probably can be quite useful. In the middle range the probabilities are going to be less precise than we would hope for.

Senator SIMPSON. I think that is right back to was it ever thus; is that not correct?

Dr. RALL. Yes.

Senator SIMPSON. That is correct.

You commented about the Hiroshima and Nagasaki populations and that this ongoing dose reassessment work there would result in marked changes in the estimates of those tables, and as a result, your quote was, "seriously affect the amount of compensation that might be awarded a claimant."

How significant a factor is this dose reassessment effort, in your view, in reaching the probabilities set forth in that report, and how much additional precision would we have after completion of the dose reassessment work?

Dr. RALL. In the first place, not all of the data for the risk coefficients come from the Japanese studies, so that some of the data stand alone without any Japanese material.

In the second place—and Mr. Jablon can comment on that in just a moment, in more detail—the dosage probably will differ by a factor of less than two from the current dose estimates.

This, however, will probably not change the probability of causation calculations by as much as a factor of two. So we do not think it is marked. We think probably a 50-percent deviation will be the most that will be expected.

Perhaps Seymour Jablon would care to add a word on that.

Mr. JABLON. Well, I think it might be a little more than that, Dr. Rall. It has been a long hard struggle to try to straighten out the dosimeasy in Hiroshima and Nagasaki, and we really hope that in some 9 or 10 months we will have some answers.

Meanwhile, because the problem is so important and seems so urgent, a number of us have been trying to estimate where it is going to wind up, but these are just estimates, and they may not be quite right.

I have made some estimates, and I said about a year ago that I thought that the risk estimates would be increased by something between 1½ and 2½ times when the dose reassessment was finished. More recently, some of the Japanese scientists in Hiroshima have made estimates which were somewhat lower.

In this work what we allowed for that, taking an average of the Japanese estimates and my estimates, and came up with an increase of about 62 percent. We allowed for that much of an increase in risk as a consequence of the reassessment.

Senator SIMPSON. There is enough uncertainty, I think, to go around, certainly, and in this range of uncertainty, could you briefly discuss—let's take three individual cases. Suppose three individuals contracted leukemia, and that based upon the individual circumstances in each case, one person's PC was 5 percent, one person's was 30 percent, and one was 50 percent. For each of these three cases, then, what is the "range of uncertainty" in those estimates?

Dr. RALL. I think we have a table on that, and perhaps Dr. Beebe can get it, and Seymour Jablon can explain.

Mr. JABLON. This is a chart of the uncertainties for all leukemia, excluding chronic lymphatic, for males—it does not say for males, but it is a figure for males. And along the horizontal here is the PC that one calculates. And then the vertical bar above that point tells us what is an interval such that we can be 90 percent sure in some sense that the true PC really is in that interval.

So, you said 10 percent was one of the numbers——

Senator SIMPSON. Five.

Mr. JABLON. Five percent. If the PC is calculated to be 5 percent—in my written testimony, I have exact numbers—we can be fairly confident that the true PC is at least, say, 3½. It might be as high as 17 or 18 percent. It is almost impossible that it should be as high as 90, 80, or 70 percent.

What were the other numbers?

Dr. RALL. Thirty percent.

Mr. JABLON. At 30 percent, the lower limit is about 25 percent; the upper limit is about 60 percent, might be as high as 60 percent. And at 50 percent, we would go from about 44 to—this looks like about 78.

Senator SIMPSON. And you call those credibility intervals?

Mr. JABLON. We call them credibility intervals. They are calculated in analogy to something that statisticians employ, called confidence intervals.

These are not confidence intervals, because much of the uncertainty really had to be guessed at. So, without getting technical about it, I feel that I can say that it would be incredible for the true value to be outside of these bounds bar a 10-percent chance.

Senator SIMPSON. Let me ask just one more question, and I shall return, because I am very interested in this. But as chairman of the Subcommittee on Nuclear Regulation, with jurisdiction over the Nuclear Regulatory Commission and also working with the areas that are also of importance to our States, Orrin, with regard to mining and milling of uranium-LOK, I am particularly interested in the potential impact of these tables, and any proposed system of compensation based on these tables, upon the commercial nuclear power industry, of which I am not a kept soul. I think my rating with the industry is 62 percent, which pleases me; at least I am somewhere between those who say, "Hell, no, I won't glow" and those who say, "Nobody has ever been killed"—and hopefully, I can remain weaving my way through that magnificent minefield. But if a worker in a commercial nuclear powerplant were to receive the maximum allowable dose under NRC's current regulations—5 rads per year, I believe—for an average working life of 30 years and then contracted a radiation-related cancer, what would that worker's PC be under the tables in this report?

Dr. RALL. It depends on the cancer that he or she developed. As a committee, we have not felt that we were asked to make these calculations, but Mr. Jablon has.

So Seymour, perhaps, could give you some numbers.

Senator SIMPSON. You waded into that one, too, eh?

Mr. JABLON. Yes, sir.

I have made a lot of calculations, and the closest I can come, quickly, to your specification is, suppose 1,000 males began work at age 20 and worked for 40 years and received 5 rads a year to the bone marrow during all of those years, for a total dose of 200 rads. This is a calculation for all leukemia. There would be about 6.8 cases of leukemia expected at baseline rate, so-called; at the normal leukemia rates in this country, there would be just under 7 in 1,000 men. There would be about 4½ excess cases induced by the radiation. The PC's would depend upon just when the leukemia arose, because the natural leukemia rate rises in older ages, whereas the induced leukemia would tend to appear earlier.

So it turns out that for the cases that arose at ages 25 or 30 or 35 or 40 or 45, the PC's would be of the order of 60 percent. How many cases would be compensable? Well, at 50 percent or more PC, 3 of the excess cases, 3 of the 4½ excess cases, would have PC's of more than 50 percent. About 2 of the 7 baseline cases would also have PC's of more than 50 percent—and so on down.

Senator SIMPSON. So you would have 6½ cases per 1,000 population, and if you had that tremendous exposure of 5 rads for a 40-year working life, you have had an additional 4½ cases within a 1,000 population?

Mr. JABLON. Yes, sir.

Senator SIMPSON. So in essence, we are involved in an effort to somehow determine 4½ persons out of 1,000 that are differing from the normal leukemia factors and exposure factors on rads and in addressing that very small group—I think it was called a vanishable figure—and I am fully aware we are talking about human beings; I do not need to go through that exercise again— that we are then reassessing the entire tort system of the United States and going to a probabilistic type of thing to reach or attempt to reach that group.

I guess what I am saying is there have been 80,000 scientific studies since Hiroshima—80,000. Are people aware of that in the United States? We have exhausted ourselves. We have piled distinction upon distinction and absurdity upon absurdity to reach something, and the more we study and the more we pursue it, we find that at least in the mainstream scientific community, a conclusion that the effects of radiation exposure at low levels over a period of time are very, very small, particularly when compared to all cancers in this country annually.

So I guess that is my—if we get to have frustration out there, I get to have mine.

The CHAIRMAN. Could I interrupt you for just a second?

Senator SIMPSON. Yes.

The **Chairman**. But that means that 5 out of the 11 would have a probability of causation ratio of better than 50 percent.

Mr. **Jablon**. Yes, sir.

The **Chairman**. That isn't small.

Mr. **Jablon**. No; but those doses are not small, either.

The **Chairman**. My point is that is significant, though.

Mr. **Jablon**. Oh, indeed.

The **Chairman**. In other words, when you talk about 5 people—and that means that probably the other 6 out of those 11 would have some aggravating factor somewhere below 50 percent, but nevertheless would have been affected.

Am I correct in that assertion?

Mr. **Jablon**. Following doses of that magnitude, only an average of a half of a case—if you can imagine a half of a case of leukemia—would have a PC less than 10 percent.

The **Chairman**. So you are saying that almost everyone there would have been affected by what happened by those rad doses?

Mr. **Jablon**. By doses of that magnitude.

The **Chairman**. Yes; and that is a pretty big magnitude. But nevertheless, that is a significant number when you consider 11 out of 1,000 people; even though it does not seem significant to those who were not involved in what is involved here, it is significant. And when you talk about 5 with a probability of risk factor above 50 percent, that is a very interesting thing. That is the only point I wanted to make. It is a small number, but it is still a big number when you consider the overall problem here.

Senator **Simpson**. I think I am concerned about the potential impact of the entire methodology on the way we establish radiation protection standards under existing law in the United States, which is already done and acceptable. If you come back here now to a situation which has been approved and not railed against by anyone as to those who work in uranium mines and mills and mess with "yellow cake," and suddenly come around with something which is totally different than that, a compensation in a different context, where an exposure of that same amount is within presently federally permitted limits, I think you are headed into some real tall grass.

Mr. **Jablon**. Do you want me to comment on that?

Senator **Simpson**. Yes, I would.

The **Chairman**. Well, let me add this, that just because a few awards are occasionally given, that does not mean we have to scrap all of the safety standards for the entire country, does it?

Mr. **Jablon**. Radiation causes cancer. I do not think anybody quarrels with that. We do quarrel a little bit about exactly how much a given dose produces. But nobody quarrels with the idea that radiation causes cancer.

Most people agree that even in small quantities, there is a certain small probability that you are going to induce a cancer by a dose. And therefore, if you want to have activity which depends upon the use of ionizing radiation, you are going to cause some harm. In theory, you are going to cause some harm. And what you want to do is to keep that harm as low as you can. But it is a great mistake to think that because the Federal standard for occupational exposure is 5 rad a year, that therefore that is a safe dose if you stay below it. It is not. There is some small probability of harm. But the people who determine these things have decided that industry can stay below 5 and accomplish the things that need to be accomplished.

[The prepared statement of Mr. Jablon follows:]

TESTIMONY BEFORE THE SUBCOMMITTEE ON NUCLEAR REGULATION OF THE SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS AND THE COMMITTEE ON LABOR AND HUMAN RESOURCES

June 11, 1985

I am pleased to be able to appear before you to help explain what has been done by the NIH Ad Hoc Working Group to Develop Radioepidemiological Tables, and particularly to share with you the results of our analysis of the accuracy of the tables. My name is Seymour Jablon and I am on the staff of the National Research Council, the operating arm of the National Academy of Sciences. I appear today, however, as a member of the NIH Working Group and not on behalf of the National Research Council. I am also a member of the National Council on Radiation Protection and Measurements, and of the Dose Assessment Advisory Group, which is an external committee appointed by the Secretary of the Department of Energy to monitor the program of assessing radiation doses to the off-site population from fall-out that resulted from atmospheric tests at the Nevada Test Site. I am also a member of the Radiation Advisory Committee under the Science Advisory Board of the Environmental Protection Agency. A full curriculum vitae is attached to this testimony.

The Working Group Report lists most, if not all, of the sources of uncertainty which affect the calculation of PC's, and shows how their magnitude can be estimated and how the several uncertainties can be combined to enable a judgment of the uncertainty in any Probability of Causation which is calculated. I will summarize and discuss briefly the more important sources of uncertainty. They are:

1. What is the appropriate baseline value? The tables utilize the All Areas incidence rates from SEER. Area-specific incidence rates are available, but only for about ten percent of the population, so that it is impossible, in general, to use area-specific rates even if that were thought to be desirable. Moreover, since the U.S. population tends to be highly mobile, even if it were desired to use area-specific incidence rates, it would often happen that the area in which a person lived at the time of onset of a cancer was different from the area in which he had spent most of his life. A host of problems would arise to which no ready solution is evident. In any case, estimates were made of the variation in incidence rates among the various areas. That variation is least for leukemia or breast cancer and greatest for liver or stomach cancer. The estimated uncertainties are included, in a site-specific way, in the overall uncertainty calculation for each cancer. In particular, the uncertainty in estimates of relative risk per rad are estimated at 10 percent for leukemia unspecified as to type; 17 percent for type-specified leukemia and cancers of bone, breast, pancreas, colon and kidney and bladder; 36 percent for cancers of the salivary glands, thyroid, lung and stomach; and 53 percent for cancers of the esophagus and liver.
2. Time Response. There is some uncertainty concerning the latent period that must elapse before there is full

expression of radiation-induced cancer. The latent period for cancers other than leukemia is almost surely at least five years and probably no more than 10. It must be assumed that there is some gradual rise from zero just after exposure to full expression after 10 or more years. The Working Group adopted a particular curve which increases smoothly from 5 years to 10; there is, however, some uncertainty in the range from 5 to 15 years and this source is also included in the overall assessment.

3. Age at Exposure. For most cancers the radiation risk varies with age at exposure. The data concerning the way in which risk varies with age at exposure are not very sturdy for most cancers and are quite inadequate for some. The associated uncertainty has been estimated and included explicitly.

4. Shape of the dose response curve. There has been considerable controversy regarding the shape of dose-response curves for X- or gamma rays - whether the response is strictly proportional to dose, that is, is linear, or increases more rapidly with increasing dose at the larger dose values. The evidence strongly favors the linear response for breast and thyroid cancers. For all other cancers the so-called linear-quadratic response was assumed. Since the exact shape of the curve is not known for these cancers, and may well not be the same for cancers of all sites, a measure of uncertainty has been introduced explicitly. This source of uncertainty is actually the

largest contributor to the overall uncertainty. The possible effect of dose-rate upon risk is also accounted for in this consideration.

5. Variation of Relative Risk with Increasing Time after Exposure. The constant relative risk time response model used assumes that, following the initial latent period of 10 years, the excess relative risk for fixed exposure is constant. The data indicate that this is at least approximately true, but since there is some uncertainty regarding this point, and uncertainty in the exact shape of the wave-like time response function for leukemia, these uncertainties too have been estimated and included in the overall assessment.

6. Effect of Exposure to Other Carcinogens and Their Interaction with Radiation. Explicit account can be and has been taken of the effect of cigarette smoking in relation to radiation exposure in the induction of lung cancer. It has not been possible to take account of other carcinogenic exposures: measures of "dose" are seldom available, and specific risk estimates per unit dose never available. The situation is redeemed somewhat by the fact that other carcinogens which interact synergistically (multiplicatively) with radiation would not, in fact, change the radiation PC calculated in the presence of other carcinogens. Nothing can be said at this time about interactions which may operate in a different way other than the interaction with cigarette smoking.

7. Effects of Recalculation of Dose Estimates for Japanese Atomic Bomb Survivors. Some - not all - of the BEIR III radiation risk estimates upon which the Tables rely are based primarily upon data concerning the atomic bomb survivors. The dosimetry system which was used to calculate those risks has been challenged and is now under investigation which will lead to revision. It seems highly probable that, in consequence of the dosimetry revision, the risk estimtes will be increased. This factor, too, has been included in the overall uncertainty analysis.
8. Dose Applicable to Particular Cases. To calculate a PC, the relevant dose must be known. Although the Working Group has, perforce, devised a procedure which assumes that the dose is known, in many instances only an approximation to the organ dose will be available and this will introduce an uncertainty in the PC finally calculated.

The various sources of uncertainty which may affect the PC as calculated have been combined and a method is shown by which the bounds of credibility can be calculated. A table, attached, shows the consequences of such calculation for two forms of cancer: leukemia, unspecified as to type, and lung cancer.

It can be observed from the table, first that although the overall uncertainties for lung cancer are larger than those for leukemia (the intervals are wider), the differences are not impressive in the face of the width of the intervals. More importantly, it can be concluded:

1. If the PC calculated is quite small - not more than 2 percent - then the PC is almost surely less than 10 percent, even taking into account all of the uncertainties mentioned.

2. If the PC calculated is fairly large - at least 30 percent - then the true PC is also large - at least 20 percent, and possibly more than 50 percent.

3. If the PC is calculated to be in the range 5 to 10 percent, it is uncertain whether the true PC is as small as 3 percent or as large as 30 percent.

New epidemiologic data continue to be produced. It can be expected that, within about two years, new data will be available concerning the Japanese atomic bomb survivors. These data will be much stronger than those upon which the Working Group has relied for two reasons: Analyses will be available in terms of a new, revised and superior dosimetry system; and at least an additional four years of follow-up data will be available, which will carry the experience through 1982, or at least 37 years after the radiation exposure to the population. The consequence of a stronger data base will be a reduction in many individual sources of uncertainty and as a result, narrowing of the uncertainty bounds for calculated Probabilities of Causation.

That concludes my prepared remarks and I shall, of course, be glad to respond to any questions that you may have.

Ninety percent Credibility Intervals for the PC

Calculated PC (%)	Leukemia, Type unspecified Limit Lower	Leukemia, Type unspecified Limit Upper	Lung Cancer Limit Lower	Lung Cancer Limit Upper
1	0.8	3	0.7	4
2	1.5	7	1.3	8
5	4	15	3	17
10	8	28	7	31
20	16	46	14	50
30	25	60	22	63
50	43	78	39	80
80	75	93	72	94
90	87	97	85	97

Senator **Simpson**. Well, I do not think the manufacturers establish that; the United States of America establishes that, based upon the public health and safety. It was not something done by the nuclear industry or the mining industry. It was done by EPA, NRC, down through the years.

But when you say, certainly, that we have radiation-caused cancer, no one is disagreeing with that. But if you take this 1981 table, here is a 1981 table of 400,000 cancers, 6,007 of them caused by radiation, and over half of those 6,007 caused by natural background. Right? Right; 2,600 caused by medical diagnostics. Right? That is right. And then development and fallout, 200. Out of 400,000 persons is what we are talking about—cancers. We are not talking about persons. Yes, we are. We are talking about persons with cancer; 200 out of 400,000. That is five-ten thousandths of that population, or cancer caused by radiation from development of fallout. So, when you are using radiation cancer, I hope people will keep in mind that over half of those are caused by natural radiation, natural background, and then the remaining bulk, like 90 percent of the remainder, are occasioned by medical diagnostics. And finally, you get down to a nub, where we are going to retool the systems of the United States to address something which I think is quite clearly uncertain.

That is what I am saying. I am not here to be a "poop." That is not my premise. But I tell you, you really, really are headed into extraordinary, I think, adventurism in causation and compensation.

And indeed, Orrin Hatch has pointed out some systems now call for overcompensation—that is, if you are going to have the defendant have the burden of proof. Some call for undercompensation if you give the plaintiff the burden of proof. So, in that frustration, we try to do something legislatively. The frustration of the courthouse. It will be with us forever as long as we function as a litigious society, I believe, is what we do.

Anyway, you have let me ramble on, and I must go. I will return. I have some other questions. I thank you, Orrin.

The **Chairman**. Thank you, Senator.

Dr. Land, could you give us an example or two?

Dr. **Land**. Mr. Chairman, I have two hypothetical examples to illustrate how the tables work. The first example——

The **Chairman**. Excuse me. I did not mean to jump around here, but I just thought it would be good at this point to give some examples. If you feel otherwise——

Dr. **Land**. Right. I have two hypothetical examples. The first example concerns an acute leukemia diagnosed in a 9-year-old girl, 4 years after exposure, at age 5, to a 5-rad bone marrow dose of low-LET radiation. In doing this example, I want to explain how the tables are used and in particular to emphasize that this calculation depends on four different factors. The first is an exposure factor, which reflects how much radiation was received by the organ in which the cancer arose, possibly as a result of that exposure.

The first chart here shows that when we use this linear-quadratic model, the exposure factor is 5 plus 5-squared over 116, which is 5.2.

The second factor——

The CHAIRMAN. These charts are at the end of your statement, for those who want to follow in the audience.

Dr. LAND. Yes, they are in the back of my statement.

The CHAIRMAN. And so could you refer to——

Dr. LAND. This will be chart 2 coming up. The first chart was the dose-response curve.

The second chart shows our estimated time distribution for an acute leukemia, if one were, in fact, caused by that exposure at age 5. This is the time distribution for when that leukemia would be diagnosed.

Now, we figure that if an acute leukemia were caused by an exposure to a 5-year-old girl, the chances are about 12 percent that it would occur exactly 4 years later.

Next chart, please.

Chart 3 shows the dependence of risk on age at exposure. This addresses a question that you raised with Dr. Rall; the risk of leukemia is greater for exposure at younger ages than at older ages, and our risk factor, 2.04, corresponding to exposure at age 5, is our estimate of the lifetime risk per 100,000 exposed, standardized to a unit value for the exposure factor.

Now, the product of these first three factors then, which is the exposure factor times the time factor times the risk factor, is 1.3, the excess risk. That is the estimated excess risk per 100,000, for radiation-induced acute leukemia, 4 years after a 5-rad exposure to a 5-year-old girl, that is, the probability of causing a leukemia like the one that appeared.

The next chart, chart 4, shows the dependence of baseline risk on age, and the PC calculation is a comparison of the excess risk with the baseline risk in the particular circumstances corresponding to that exposure. The curve is a very wavy line because it is based on actual data, that is, the age-specific leukemia rates among women in the United States.

We calculate the relative excess as the quotient of these factors, 1.3 divided by 2.22, which gives a relative excess of .586, and from this, we calculate the PC to be 37 percent.

Now, the point of this exercise, one of the points of this exercise, is to show that given the tables, it is rather simple to calculate a PC.

But the next chart may help to give a better intuitive understanding of the PC. Now, this chart, which is chart 5, is really——

The CHAIRMAN. May I ask you one question. On this illustration you are giving, you are considering a low dose of 5 rads, right?

Dr. LAND. Five rads, yes.

The CHAIRMAN. That would be a low dose.

Dr. LAND. Well, to a 5-year-old girl, no, I don't think so.

The CHAIRMAN. But to you, it would be a low dose, you are saying?

Dr. LAND. I am sorry?

The CHAIRMAN. I mean, would that have been a likely dose? Is it considered low-level radiation, is my question. I guess maybe I am not asking it in a very articulate way. But that would be considered a low—level dose of radiation?

Dr. **Land**. It is a low-level dose compared to what the more heavily exposed A-bomb survivors received. It is a very high dose compared to what someone might get in ordinary life.

The **Chairman**. Go ahead.

Dr. **Land**. This graph——

The **Chairman**. My point is—and maybe I just do not understand it—but my point is that under the circumstances, it would be considered a low-level radiation dose, the one-time 5 rad.

Dr. **Land**. Yes.

The **Chairman**. OK.

Dr. **Rall**. Perhaps I can say one thing, and that is that the leukemias are particularly radiogenic, and they are particular susceptible when they are at a young age. So Dr. Land has chosen an example in which you will probably get about the highest probability of causation for any tumor caused by that amount of radiation.

The **Chairman**. And that is 37 percent in this particular case.

Dr. **Rall**. Yes. But if you were to look at many other circumstances, someone who was exposed at the age of 30 and developed leukemia 10 years later, it would be much, much smaller, or someone exposed at the age of 20 and developed breast cancer, the PC's would be much smaller.

The **Chairman**. I am sorry. Go ahead.

Dr. **Land**. The next slide shows what would happen if we take the excess risk as distributed over time and add it to the baseline risk.

The **Chairman**. This is chart 6?

Dr. **Land**. This is chart 6. And the lower curve is the baseline risk, that is, the age-specific risk of leukemia without any exposure.

The **Chairman**. You say it is higher, the younger the age at exposure, and the risk diminishes as you get older?

Dr. **Land**. Well, yes; just from population statistics, the childhood leukemia risk is quite high, relatively high, at very young ages; it decreases, and teenagers have the least risk, and then it goes up. Then, on top of that, we put this excess risk that we might expect from an exposure of 5 rads at age 5.

Now, that excess risk begins about 2 years after exposure, and it goes to a peak at about age 9 or 10, and then it diminishes until after about age 30, it really is not there anymore. Leukemia is one of the radiation-induced cancers that seems to have a limited period of risk.

And as for the PC calculation, the point of all this is that we take the excess risk, which is the total risk minus the baseline, 1.3; and we divided it by the total risk, which is the baseline plus the excess, and as before, we get 37 percent.

The idea is to show the PC calculation in terms of risk with and without exposure, rather than as the product of several factors.

Now, these two representations are algebraically equivalent, but for most cancers, that is, cancers other than leukemia and other than bone cancer, it is easier, and it requires less in the way of tables, to just do things the first way, in terms of "R," one relative excess.

My second example concerns a lung cancer diagnosis in a 55-year-old man who received at age 28 a 40-rad bronchial dose of low-

LET radiation. I would first like to carry out the calculation assuming that we have no information on the man's smoking history, so that we must assume that his baseline risk corresponds to the average risk among all U.S. males of his age. And afterward, I will just demonstrate how information on smoking history is taken into account.

Now, for lung cancer, like leukemia, the risk from low-LET radiation is assumed to be proportional to this linear-quadratic function of dose, and the appropriate exposure factor, therefore, is 40, plus 40-squared—which is 1,600—over 116, and that is 53.8.

Now, the relative excess, "R," is assumed to reach its full value after 10 years. We are dealing with one of the cancers for which the constant relative risk model is assumed. Diagnosis occurred well after 10 years. The time factor is therefore just one; we can forget about it.

Now, the ratio, the excess over the baseline, is a constant thing, and so it is not necessary to table the excess and the baseline separately. We just table a sort of standardized relative excess, and that value, K, for an exposure at age 28 to a man is 0.000619, which is, again, from the table. And we can calculate the relative excess as the product of the exposure factor, the time factor, and this standardized relative excess, 53.8 times 1 times 0.000619, and that is 0.03, and the PC is just 0.03 over 1 plus 0.03, which is 3 percent.

The calculation is computationally simpler than that from leukemia. I think it is intuitively less appealing, but the graph here, the chart, which I believe is chart No. 7——

The CHAIRMAN. Would this apply to, say, uranium miners, this illustration?

Dr. LAND. Yes—I am sorry. It would not apply to uranium miners in one sense. The time consideration would apply, but because the uranium miner is exposed to——

The CHAIRMAN. They get high-LET.

Dr. LAND [continuing]. They get high-LET radiation, and so we use a different table.

The CHAIRMAN. But you do not know what that does.

Dr. LAND. Well, we do have a formula for that, but we borrowed it.

The CHAIRMAN. OK.

Dr. LAND. We borrowed it from an ICRP publication. We felt that these two had to be treated separately, the high-LET and the low-LET.

The CHAIRMAN. All right.

Dr. LAND. Here, we have the excess, which starts increasing about 5 years after the exposure, and then after about 10 years, it has a constant ratio to the baseline, and the PC is, again, the excess divided by the total risk, which you can see there on the chart.

Now, if we know that the subject was a lifelong nonsmoker, the effect here is not—this has nothing to do with his excess risk, because for low-LET radiation, and this does not seem to be true for high-LET radiation, smoking and radiation do not seem to interact. They seem to just add to one another, so the effect of being a nonsmoker is to reduce his baseline risk. A lifelong nonsmoker has about one-seventh the lung cancer risk of the general population.

So we are dividing here the excess of 5.3 by a much smaller number, and we get a PC of 17 percent, in this case.

Now, just let me go through one more which will be quite fast. I will just mention that in the case of someone who is known to be a heavy smoker, the effect is just the opposite. The excess again stays the same, but the baseline is much greater. The baseline in a heavy smoker is between four and five times higher than in the general population, and the PC is 1 percent.

I have this example also in my testimony.

Mr. Chairman, this concludes my part of the testimony. If you have any questions, I will be happy to answer them.

The CHAIRMAN. OK, thank you.

[The prepared statement of Mr. Land follows:]

FOR RELEASE UPON DELIVERY

STATEMENT OF

CHARLES E. LAND, Ph.D.

HEALTH STATISTICIAN

NATIONAL INSTITUTES OF HEALTH

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

AND

THE ENVIRONMENT AND PUBLIC WORKS SUBCOMMITTEE ON NUCLEAR REGULATION

UNITED STATES SENATE

JUNE 11, 1985

Senator Hatch, Senator Simpson, and Members of the Committee and the Subcommittee:

I am a member of the NIH working group that developed the radioepidemiological tables and am pleased to discuss the Probability of Causation (PC) calculation in some detail. As Dr. Rall has explained, the PC calculation depends upon four different factors. The first is an exposure factor, reflecting how much radiation was received by the organ in which cancer arose, possibly as the result of that exposure. The second is a time factor, which bears on the plausibility of a causal association in terms of the elapsed time between exposure and cancer diagnosis. A causal association might be considered implausible, for example, if the elapsed time were very short or very long. The third factor reflects the sensitivity to radiation carcinogenesis of the organ in question; this factor also varies by age at exposure and by sex. The first three factors together determine the risk of radiation-induced cancer. The PC calculation is essentially a comparison of that risk with the fourth factor, the baseline probability that the cancer would have occurred anyway, in the absence of the exposure. This factor varies by sex and age at diagnosis, and also can be influenced by exposure to carcinogens other than radiation, like tobacco smoke.

I will use two hypothetical examples to illustrate how the four factors are determined, and how they are combined to produce a PC estimate.

My first example concerns an acute leukemia diagnosed in a 9-year-old girl, 4 years after exposure, at age 5, to a 5-rad bone-marrow dose of low-LET radiation.

For acute leukemia, the risk from low-LET radiation is proportional to

$$F(D) = D + D^2/116.$$

This dose-response curve is shown in Chart 1. The exposure factor for a dose of 5 rad is

$$F(5) = 5 + 25/116 = 5.22.$$

Chart 2 shows the estimated distribution of the excess risk over time after exposure, for exposure at age 5. The graph corresponds to the column for exposure at age 5 in Table X-1-D on page 158. According to the graph, a causal connection would be relatively implausible, based on time considerations alone, if the diagnosis had occurred as early as 2 years, or as late as 15 years, after exposure, but relatively plausible for diagnosis between 3 and 10 years. The time factor $T = .122$ corresponding to an elapsed time of 4 years reflects our estimate of the conditional probability, given that an exposure at age 5 really did cause an acute leukemia, that diagnosis would occur 4 years later and not at some other time.

Chart 3 shows the dependence of risk on age at exposure. It corresponds to the second column in the body of Table X-1-E, on page 167. The factor $E = 2.04$ is our estimate of the lifetime risk, per 100,000 exposed, for an exposure at age 5 such that the exposure factor is unity, and assuming that no other cause of death intervenes.

The product of the first three factors,

$$F \times T \times E = 5.22 \times .122 \times 2.04 = 1.30,$$

is the estimated risk per 100,000 of a radiation-induced acute leukemia, 4 years after a 5-rad exposure to a 5-year-old girl.

The fourth chart shows the dependence of baseline risk on age, and corresponds to the second column in the body of Table X-1-F on page 168. The risk of acute leukemia among 9-year-old girls generally is I = 2.22 per 100,000.

As mentioned previously, the PC calculation is based on a comparison of estimated excess and baseline risk. The relative excess, R, is the ratio of these two numbers:

$$R = (F \times T \times E)/I = 1.30/2.22 = .586.$$

The PC is calculated from R as

$$PC = R/(1+R) = .586/1.586 = 37\%.$$

The above exercise shows the simplicity of the PC calculation given basic information about exposure and diagnosis, and given the tables. Another chart may help to give a better intuitive understanding of the PC.

If we take the time-to-response distribution in Chart 2, move it 5 years to the right, and multiply it by the exposure factor F = 5.22 and the risk factor E = 2.04, we get a graphical representation of excess risk by age. This is shown in chart 5. The next chart shows the effect of adding that excess to baseline risk. The graph of total risk (baseline plus excess) does not deviate from the baseline graph until age 7, 2 years after exposure. It increases to a peak between ages 9 and 10, and then declines more gradually until, at age 35 or so, it is essentially back at baseline. For diagnosis at any particular age, the PC is that proportion of the total risk attributable to the exposure. For example, at age 9 the total risk per 100,000 is 3.52, compared to a baseline of 2.22. The excess, therefore, is 1.30, and the PC is

$$PC = Excess/Total = 1.30/3.52 = 37\%.$$

* * *

The above representation of the PC, in terms of excess risk and total risk, is algebraically equivalent to the previous one given in terms of R. For most cancers, however, it is easier, and requires less in the way of tables, to calculate R directly than to calculate excess risk and baseline risk separately.

My second example concerns a lung cancer diagnosis in a 55-year-old man who received, at age 28, a 40-rad bronchial dose of low-LET radiation. I would first like to carry out the calculation assuming that we have no information on the man's smoking history, so that we must assume that his baseline risk corresponds to the average risk among all U.S. males of his age. Afterward, I will demonstrate how information on smoking history is taken into account.

For lung cancer, like leukemia, the risk from low-LET radiation is assumed to be proportional to

$$F(D) = D + D^2/116,$$

and therefore the appropriate exposure factor is

$$F = F(40) = 40 + 1600/116 = 53.8.$$

The relative excess R is assumed to reach its full value after 10 years. Since diagnosis occurred well after that, the time factor T is one:

$$T = T(27) = 1$$

Note that for lung cancer, unlike leukemia, the time factor T does not represent the probability distribution of time to diagnosis. It simply reflects the fact that, under the constant relative risk time response model described by Dr. Rall, the ratio, R, of excess to baseline risk is constant over time 10 or more years after exposure, but increases gradually to that value from its initial value of zero immediately after exposure. Because that ratio is constant, it is unnecessary to tabulate factors E and I separately, as was done for leukemia. Their ratio, K = E/I, depends only on sex and age at exposure, and is given in the first column in the body of Table X-9-A on page 240. For exposure at age 28 the value is

$$K = K(28,m) = .000619.$$

The relative excess R is the product of the three factors whose values were just obtained,

$$R = F \times T \times K = 53.8 \times 1 \times .000619 = .0333,$$

and the PC is

$$PC = R/(1+R) = .0333/1.0333 = 3\%.$$

The PC calculation for lung cancer is computationally simpler than that for leukemia, but it may be intuitively less appealing. Chart 7 shows risk, with and without exposure, as functions of age, in a manner comparable to the final set of curves presented for the leukemia example. The graph shows that the total risk departs from the baseline risk at age 33, 5 years after exposure, and increases somewhat faster than the baseline until age 38, 10 years after exposure. Thereafter, total risk and baseline risk are in the constant proportion (R+1):1. At age 55, the total cancer risk per 100,000 is 164.0, as compared to the baseline rate of 158.7. Thus the excess is 5.3, and the PC is

$$PC = Excess/Total = 5.3/164.0 = 3\%.$$

Now suppose that we know the subject to be a lifelong non-smoker. His excess risk remains the same, because epidemiological data indicate that smoking and low-LET radiation are additive in their effects on lung cancer risk. His baseline risk, however, is less by the factor W = 6.81, obtained from Table X-9-B on page 241. Chart 8 shows the revised relationship of risk to age. At age 55, the baseline risk is 158.7/6.81 = 23.3, and the total risk is 23.3 + 5.3 = 28.6. The PC is

PC = Excess/Total = 5.3/28.6 = 19%.

If, in Chart 7, the ratio of total to baseline risk after age 38 is 1+R, the ratio in Chart 8 must be 1 + R x W, where R is the relative excess computed without information on smoking. It follows, therefore, that the relative excess appropriate for a non-smoker is W times the value for a "typical" U.S. male. The calculation from the tables of the PC for a non-smoker is therefore as follows:

R = F x T x K x W = 53.8 x 1 x .000619 x 6.81 = .227,

PC = R/(1+R) = .227/1.227 = 19%.

Finally, I would like to expand the example to include the case in which the cancer patient was a heavy smoker. From Table X-9-B on page 241, the factor W for a man smoking 40+ cigarettes per day is W = 0.287. The relative excess, then, would be

R = F x T x K x W = 53.8 x 1 x .000619 x 0.287 = .00956,

from which the PC is

PC = R/(1+R) = .00956/1.00956 = 1%.

As in the case of a non-smoker, the excess risk due to radiation is unchanged, it remains at 5.3 per 100,000. The baseline risk, however, is higher than it is among non-smokers or the general population. It is

158.7/.287 = 553.0.

Thus, the total risk is 558.3 per 100,000 and the PC is

PC = Excess/Total = 5.3/553.0 = 1%.

* * *

This concludes my part of the testimony. If there are any questions, I will be happy to answer them.

CHART A

Acute leukemia diagnosed in a 9-year-old girl, 4 years after a 5-rad dose of low-LET radiation to bone marrow, at age 5.

$D = 5$

$F(D) = 5 + (5)^2/116 = 5.22$

$A_1 = 5, \; Y = 4$

$T(A_1, Y) = T(5,4) = .122$
(Table X–1-D, pg. 158)

$S = f$

$E(A_1, S) = E(5,f) = 2.04$
(Table X–1-E, pg. 167)

$\text{Excess Risk} = F(D) \times T(A_1,Y) \times E(A_1,S)$

$= 5.22 \times .122 \times 2.04 = 1.30$

$A_2 = 9$

$\text{Baseline Risk} = I(A_2,f) = 2.22$
(Table X–1-F, pg. 168)

$R = \text{Excess/Baseline} = 1.30/2.22 = .585$

$$PC = \frac{R}{1 + R} = \frac{.585}{1.585} = 37\%$$

CHART 1

Acute leukemia risk in females following a bone marrow dose of 5 rad at age 5.
Calculation of F (D).

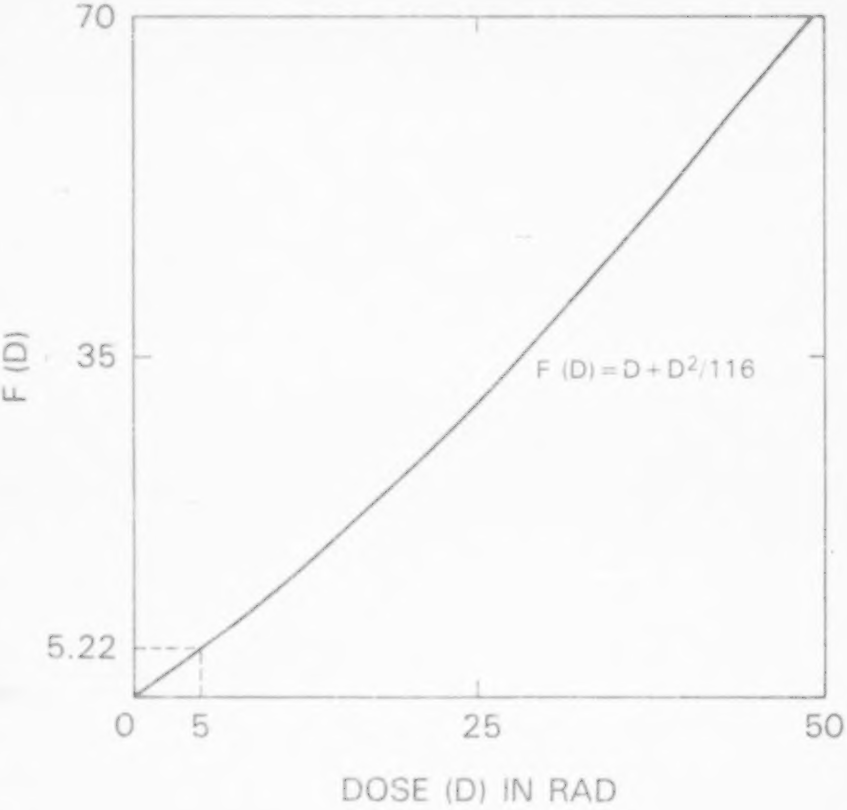


CHART 2

Acute leukemia risk in females following a radiation exposure at age 5.

Determination of time-to-response probability for 4 years after exposure.

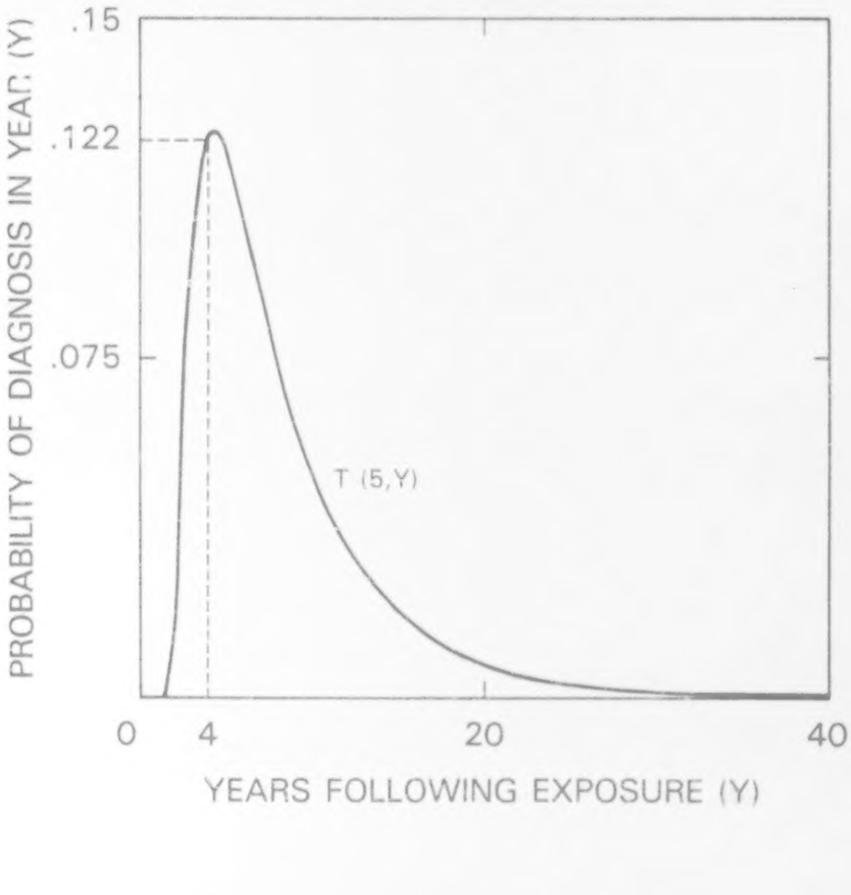


CHART 3

Acute leukemia risk in females following a radiation exposure at age 5.
Determination of risk coefficient.

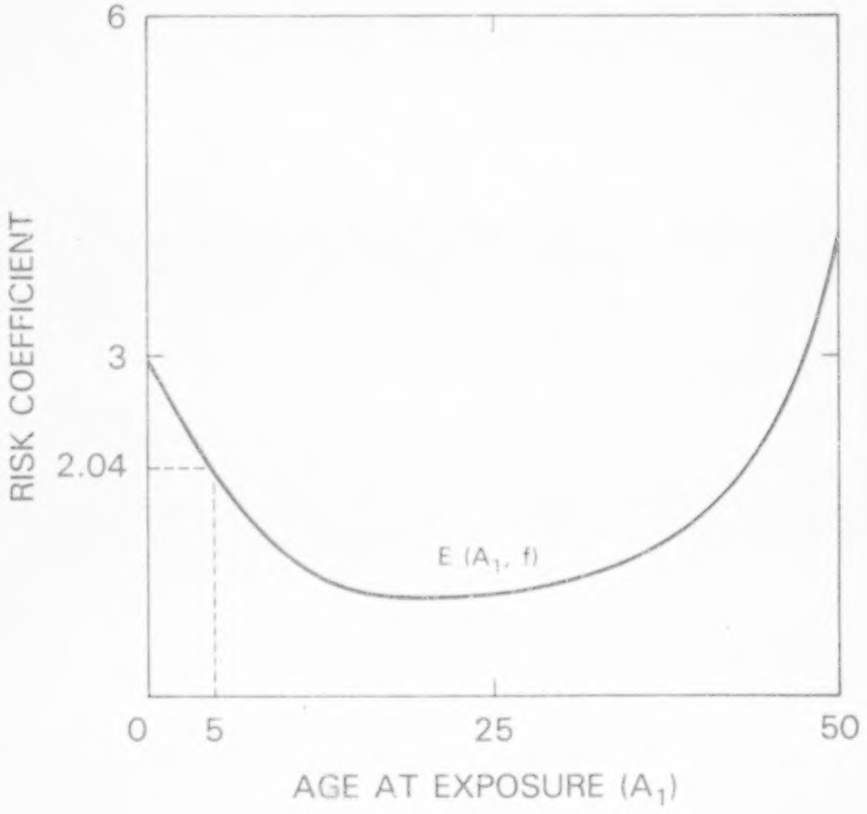
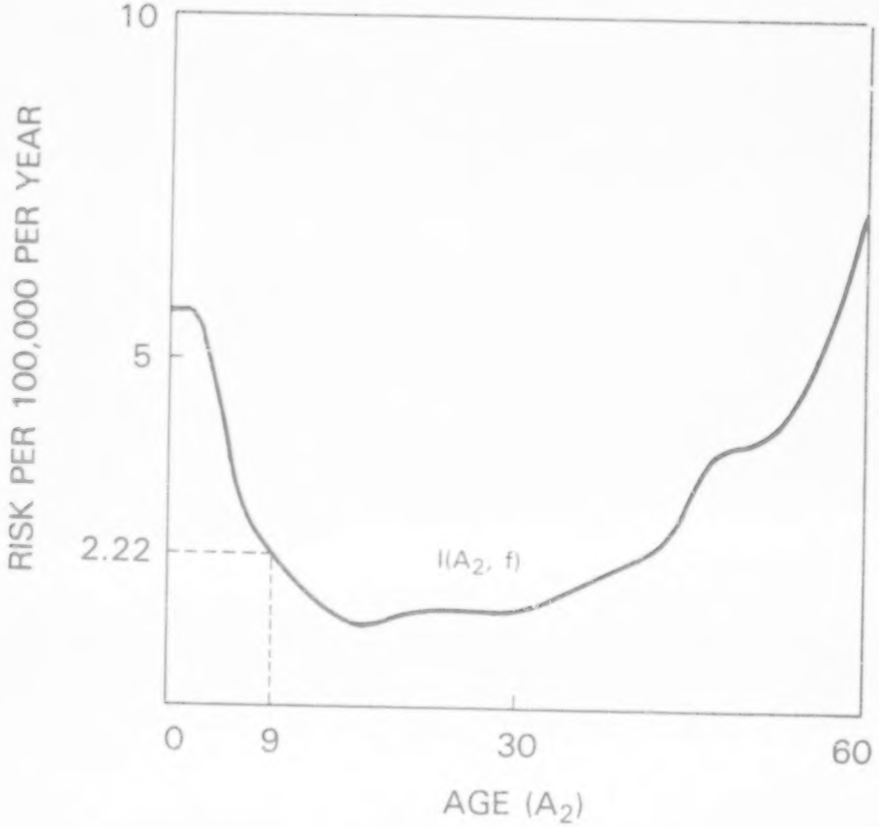


CHART 4

Acute leukemia risk in females.
Determination of baseline risk at age 9.



Acute leukemia risk in females following a 5-rad bone marrow at age 5.

Determination of excess risk at age 9.

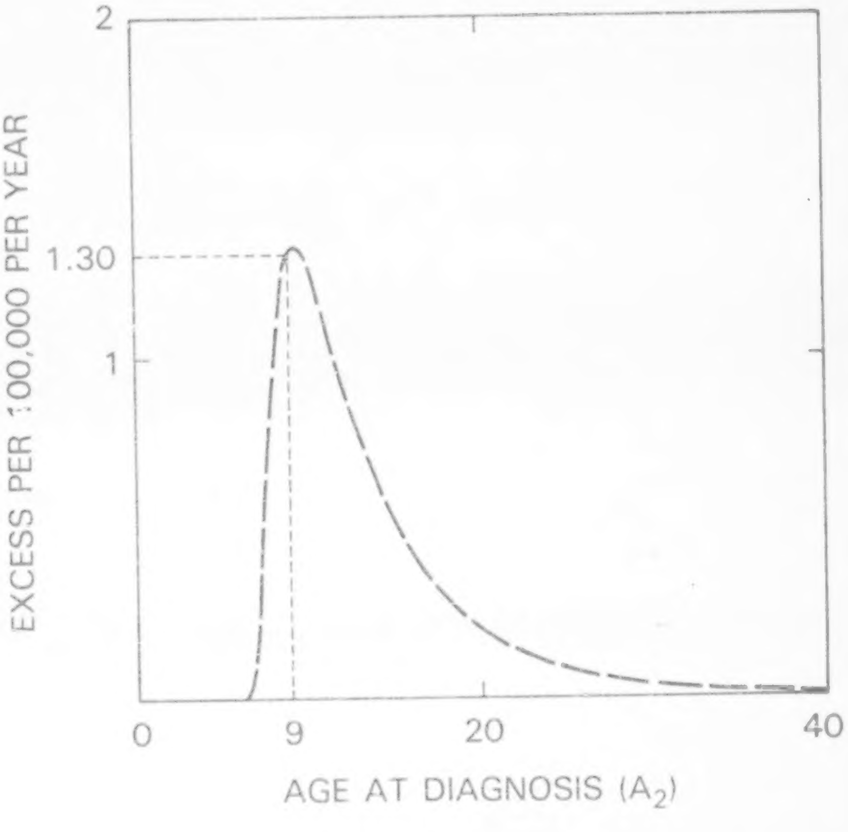


CHART 6

Acute leukemia risk in females following a 5-rad dose to bone marrow at age 5.

Calculation of PC for diagnosis at age 9.

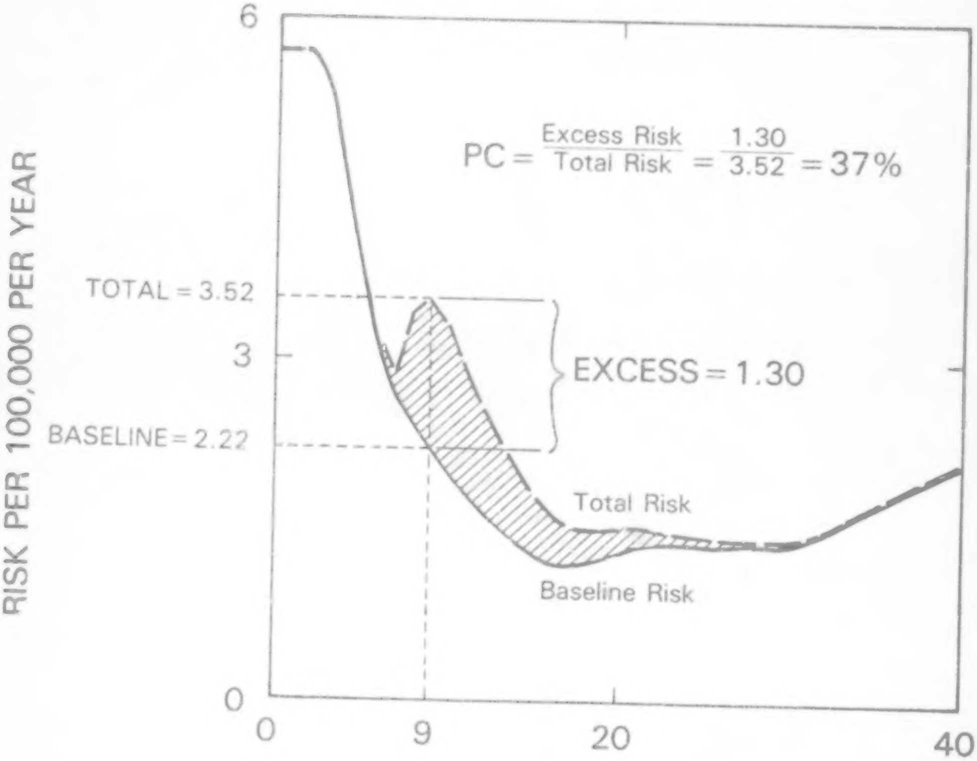


CHART B

Lung cancer in a 55-year-old man, following a 40-rad lung dose of low-LET radiation at age 28.

$D = 40$

$F(D) = D + D^2/116 = 40 + 1600/116 = 53.8$

$Y = 27$

$T(Y) = T(27) = 1$

$A_1 = 28, S = M$

$K(A_1, S) = K(28, M) = .000619$ (Table X–9-A, pg. 240)

If we have no information on smoking,

$R = F \times T \times K = 53.8 \times 1 \times .000619 = .0333$

$$PC = \frac{R}{1 + R} = \frac{.0333}{1.0333} = 3\%$$

If the subject is a lifelong nonsmoker,

we introduce the adjustment factor

$W = 6.81$ (Table X–9-B, pg. 241)

$R = F \times T \times K \times W = 53.8 \times 1 \times .000619 \times 6.81 = .227$

$$PC = \frac{R}{1 + R} = \frac{.227}{1.227} = 19\%$$

If the subject is a heavy smoker

$W = .287$ (Table X–9-B, pg. 240)

$R = F \times T \times K \times W = 53.8 \times 1 \times .000619 \times .287 = .00956$

$$PC = \frac{R}{1 + R} = \frac{.00956}{1.00956} = 1\%$$

CHART 7

Lung cancer risk in males, with no information on smoking, following a 40-rad dose to the lung of low-LET radiation at age 28.
Illustration of PC for diagnosis at age 55.

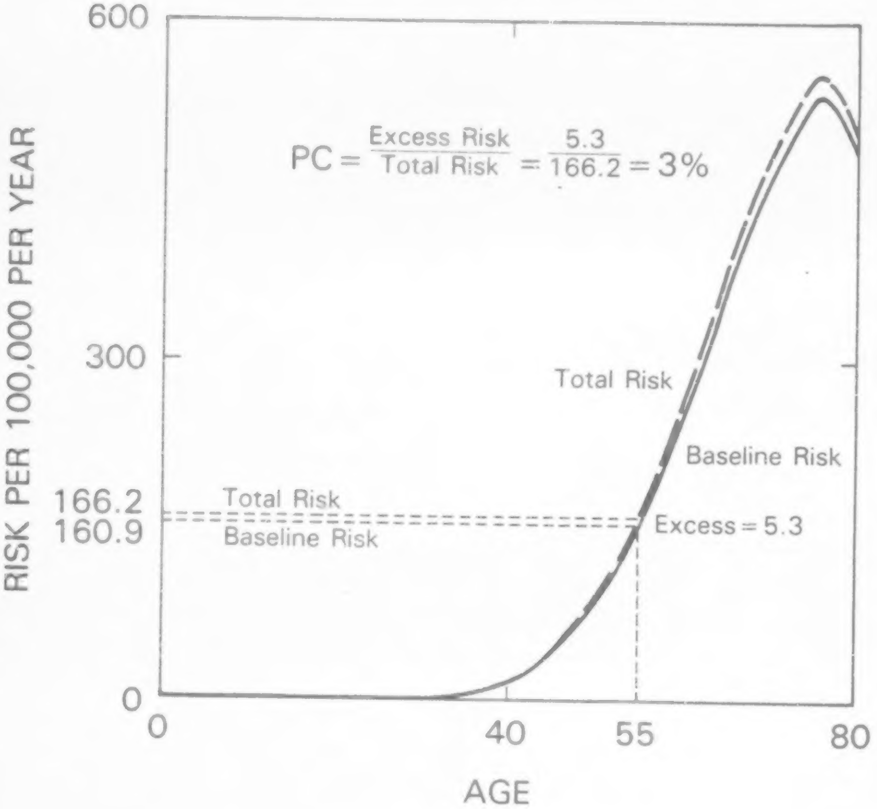
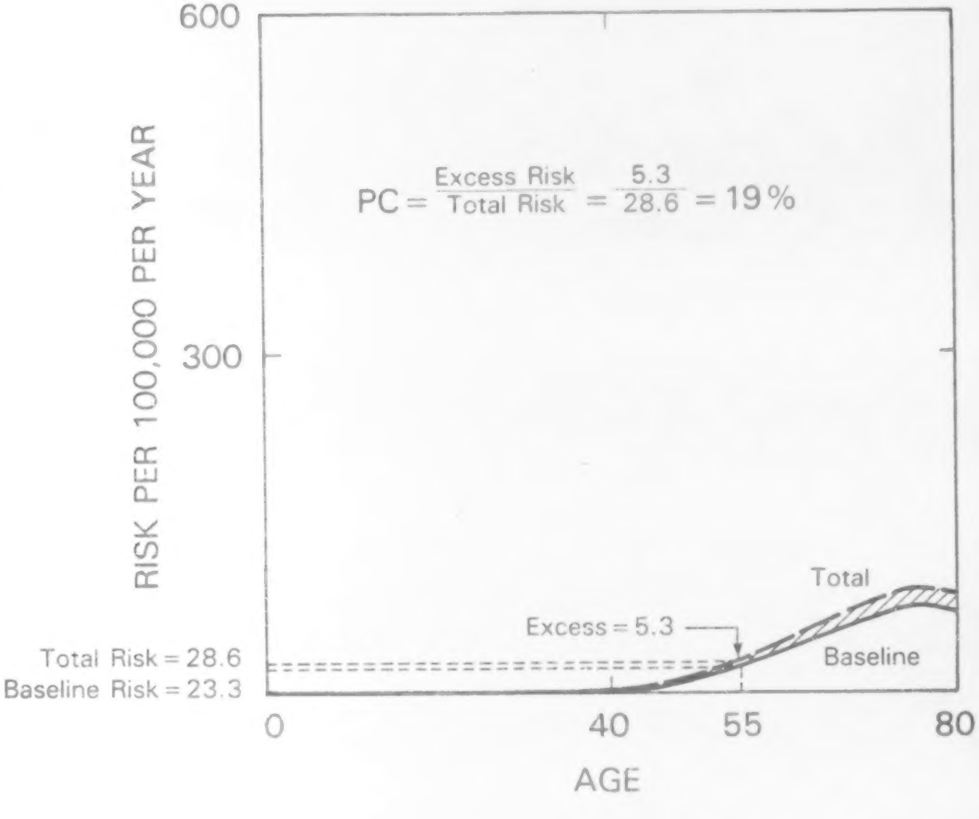


CHART 8

Lung cancer risk in non-smoking males following a 40-rad dose to the lung of low-LET radiation at age 28.

Illustration of PC for diagnosis at age 55.



The CHAIRMAN. Dr. Beebe, do you have anything to add here today?

Dr. BEEBE. I think I will pass, and I will be happy to answer your questions.

The CHAIRMAN. OK, maybe we could just ask some questions and we will put all of your statements into the record as though fully delivered.

Dr. Rall, at our preliminary hearing on the tables last September, your formal statement contained the following sentence:

> Given these limitations on the validity of the radioepidemiological tables, no court should consider the tables reliable evidence that a specific individual's cancer was caused by radiation exposure.

Did you write that statement, and does that still represent your views?

Dr. RALL. That statement represented the views of the Department last fall.

The CHAIRMAN. What about yourself?

Dr. RALL. I cannot really subscribe to that statement, because it seems to me the tables represent the best effort of a large number of people who surveyed the world literature and tried to come out with a consensus as to what these probabilities are. It is a very difficult, complicated problem, and fraught with uncertainties, but I fail to see why it is better to disregard a consensus and adopt an ad hoc approach to every case.

The CHAIRMAN. Some courts—or should I say, some legal scholars—have argued that the courts should not rely solely on probabilistic evidence regarding radiation cancer claims. They say that there must also be, to use the term, "particularistic" or clinical evidence.

Is it not true that this particularistic or clinic evidence simply does not exist in the case of the atmospheric tests, for instance?

Dr. RALL. I am unclear as to what that means. In the first place, I do not know why one shies away from probabilities when, as I understand it, tort law explicitly says "more likely than not," which is a probabilistic statement.

Although there might be special cases involved for any particular individual, smoking represents the only confounding agent for which data are available and we have used that in the tables. As a general idea of what the probabilities are most likely to be, the tables should be useful.

The CHAIRMAN. I agree on the probabilities. Do we have any clinical evidence that such cancers exist?

Dr. RALL. I am sorry?

The CHAIRMAN. Do we have any clinical evidence to substantiate the cancer claims?

Dr. RALL. You certainly cannot examine a cancer histologically or biochemically in such a way as to enable you to say whether or not it is radiation-induced.

The CHAIRMAN. Yes. The courts have dealt with a number of radiogenic cancer cases, and the experts in these cases have rendered opinions concerning whether radiation caused the cancers in question. And I think my question to you is upon what were these testimonies based? Did these experts make some sort of a formal or in-formal probability of causation calculation? Could they have done anything else?

Dr. RALL. I do not know that they could have done anything different than we did, which is look at the available evidence and try and make the same calculations we have. And I would think every expert would have to do roughly the same thing.

There is no secret source of information available.

The CHAIRMAN. I see. Now, you have testified that considerable uncertainties attend these probability of causation estimates, and the calculations, it seems to me, seem to depend upon a number of theoretical assumptions. Do you feel that the uncertainties are so great that the courts should not credit this evidence?

Dr. RALL. No; I do not. As I explained, I think at the higher and lower PC calculations, they are reasonably reliable. But if the courts do not use the tables, I don't know what else they would do, because they would only then ask an expert to recreate in that particular case essentially what the tables have tried to do for you.

The CHAIRMAN. Well, put another way, the courts are not supposed to award damages to people who cannot prove their cases. Do you think that the science is so uncertain that the court should throw out all low-level radiation cancer claims for insufficient evidence?

Dr. RALL. No, I do not think so, although it depends on how you define "low". In the case that Dr. Land presented, a relatively low dose of 5 rads produced a 37-percent PC. I do not know whether you want to compensate it or not, but if that individual had gotten 10 rads, undoubtedly, her PC would have been, I suspect, over 50 percent.

This certainly satisfies the "more likely than not."

The CHAIRMAN. Well, let me ask you this. Do you then feel that the probability of causation method that we are talking about here is the best available method for addressing the issue of radiation cancer causality?

Dr. RALL. Yes, I do. We would not have spent 2 years working on this if we did not think this was scientifically reasonable and feasible.

The CHAIRMAN. I understand that the data on the effects of radiation are far more comprehensive than the data pertinent to other toxins. What is the applicability of the probability of causation method for other toxins, and could tables be constructed for that?

Dr. RALL. The only one that would at all be possible would be cigarette smoking. We already have something approximating a probability of causation for lung cancer as a result of cigarette smoking.

The CHAIRMAN. So you are saying that we have enough data and information and evidence so that the probability of causation theory actually should apply, and the only other area where you think there is enough evidence or data would be in the area of smoking.

Dr. RALL. That is correct. There are a variety of substances that are known to be carcinogenic—asbestos, benzene, and a variety of other chemicals—but (*a*) we almost never know the dose that an individual receives, and (*b*) we haven't the faintest notion what the risk estimate is, that is, if 1,000 people exposed to so much benzene, what fraction will get leukemia is totally up in the air. There does not appear to be any foreseeable way to estimate doses and get the epidemiologic data to make the tables of probability of causation for other environmental hazards, that I am aware of, with the single exception, as I mentioned, of cigarette smoking.

The CHAIRMAN. But here, with the work your committee has done and the evidence you have presented today, you believe that this data should be admissible in court?

Dr. RALL. Yes, sir.

The CHAIRMAN. Is it not true that some people who receive no more than the doses allowable under current safety standards might have substantial probability of causation?

Dr. RALL. Yes. Mr. Jablon detailed a rather improbable case, but it is possible that an individual working in a nuclear power industry who received the maximum allowable 5 rads a year for 40 years, and then developed a particular cancer such as leukemia, might have a probability of causation which according to these tables, calculated to be greater than 50 percent.

The CHAIRMAN. What does this fact, then, imply as far as the safety standards are concerned? Should they necessarily be tightened.

Dr. RALL. That is a policy issue that I would not be competent to comment on, other than to say that there is a risk connected with everything we do, and it is not possible to reduce the risk to zero for anything. As you pointed out, we are exposed to background radiation of a 10th or more of a rad per year. We get on the average almost a 10th of a rad from diagnostic x ray, which is extremely important. It is just not possible to get rid of radiation. So the problem as to whether the safety standards should be reduced is a complicated one that I am not competent to give a good answer to.

The CHAIRMAN. Let me interrupt my questioning to turn to Senator Metzenbaum, who has to get to two other committees.

Senator METZENBAUM. I do appreciate your cooperation, Mr. Chairman; I have two other committees meeting. But I am much concerned about this study.

First, Dr. Rall, let me ask you about the objectivity of the committee itself. The charge has been made by Dr. Pauling that the panels conducting these studies have always been stacked with government scientists too concerned with expressing pro nuclear, radiation is good for you, party lines. Their objectivity on the issue can be looked at as little more than a fraud. The current studies being completed by Senator Orrin Hatch's Epidemiological Panel is no exception. Any time you have such pro Government scientists as Drs. Yalow, Land, Upton, Beebe, and Jablon, the truth concerning the true impacts of fallout exposure will be sorely lacking, and their results are biased from the beginning.

I do not want to make a judgment call on that. I respect Dr. Pauling. But I think you all should be given an opportunity to speak to the objectivity of the committee, in the first instance, and that is, have all of those who are on this committee been identified with the Government. I gather you yourself have not been; is that correct?

Dr. RALL. I have been employed by the National Institutes of Health for 30 years.

Senator **Metzenbaum**. For 30 years.

Dr. **Rall**. But I do recall, perhaps 25 or 26 years ago, writing an editorial for the Archives of Internal Medicine—this, as you will recall, is a long time ago—pointing out the dangers of radioactivity and the hazards associated with it.

So a long time ago, I was concerned about the potential hazards of radiation. I think you will find that Drs. Land and Beebe and Jablon are epidemiologists who have been involved in looking at the best source of data for radiation-induced cancer; namely, the Japanese people who were exposed at Hiroshima and Nagasaki.

Senator **Metzenbaum**. I guess my real question is, I recollect in my own lifetime when Dr. John Gofman out on the west coast, at Lawrence Livermore, was called upon to do a study on the safety of nuclear energy and its usage for the Government. And I remember very well that he came to the wrong conclusion and said that it was not safe. And almost overnight, his subvention from the Government was terminated, and his relationship with the Government came to a conclusion.

Therefore, I think it is important, if you are going to have an objective study, that we look to see whether the hand that is feeding the mouths of each of those who are making the study, since there are Government dollars involved in the final impact on this issue, whether—Dr. Beebe is with the National Cancer Institute—is that correct?

Dr. **Beebe**. Yes.

Senator **Metzenbaum**. And Dr. Jablon is with the National Research Council; is that Government-funded, Dr. Jablon?

Mr. **Jablon**. Most of our funding does come from the Government, yes, sir.

Senator **Metzenbaum**. And Dr. Land is with the National Cancer Institute.

Now, I am not sitting here saying that Government officials cannot have objectivity, but I am a realist enough to understand that there is a Government financial interest in this whole issue. And there is one other person, a woman, I believe—is it Dr. Yalow——

Dr. **Rall**. Yes.

Senator **Metzenbaum**. And with whom is she identified?

Dr. **Rall**. The Veterans' Administration.

Senator **Metzenbaum**. The Veterans' Administration.

So, were there any outside scientists who were not part of the——

Dr. **Rall**. Dr. Arthur Upton is a professor at New York University, and Prof. Oddvar Nygaard is head of the division of radiation biology at Case Western Reserve. These have no relationship to the Government.

Senator **Metzenbaum**. Do either or both of them operate on substantial Government subvention?

Dr. **Rall**. I suspect they probably do. It is rather difficult to do research these days absent support, and since in the biomedical sciences, the National Institutes of Health accounts for some 60 percent of the support, it would be almost impossible for them to do research without NIH support.

I should say, sir, that my funding and the funding of the National Institutes of Health, as far as I understand it, is unrelated to whether radiation compensation is paid to anyone and whether radiation is a major cause of cancer or a minor cause of cancer. It is totally irrelevant to my occupation for the last 30 years.

Senator **Metzenbaum**. I am not questioning your integrity. I am questioning the propriety of having people, all of whom work for the Government, or who depend upon the Government for livelihood, be the only ones who sit on a committee of inquiry of this kind. Now, Dr. Upton, I have here before me the Salt Lake Tribune of November 2 and 3, 1982, which reads.

> The testimony of Dr. Upton, chairman of the department of environmental medicine at New York University, was an attempt by the Government to refute claims that radioactive fallout from nuclear weapons testing in Nevada caused cancer in residents downwind of the test site.

So that it was quite obvious that he was testifying against the claimants in that particular instance.

Let me ask you a question. Dr. Jablon has stated today that there is no question radiation causes cancer. But another member of your committee, Dr. Yalow, has been quoted as saying, "Low-level radiation is safe," and goes on to say, "You people in Utah are the healthiest in the Nation, and if anything, it seems as if the radiation is good for you."

Would you care to comment on that, Dr. Rall, or anyone?

Dr. **Rall**. Dr. Yalow is fond of hyperbole. But I think we run into trouble when we use terms that we do not define, such as "low," in the sense that we do not know whether 1 rad of radiation will cause cancer or not. We do not really know for sure whether 5 rads will. We know that 100 rads may cause cancer. So that, when you are talking about low-level, if by "low," you mean 1 rad or less, there is no evidence one way or the other.

Senator **Metzenbaum**. But the assumption of these tables, as I understand it, is that the exposure from a single, intense flash of an atomic weapon does not differ in its impact on humans from the long-term, low-level exposure to uranium dust by workers at the Fernhold, OH, Department of Energy facility.

Is that a correct statement?

Dr. **Rall**. It exaggerates, perhaps, a few things. The radiation delivered by the atom bombs at Hiroshima and Nagasaki was delivered at the rate of roughly 10,000 rads per minute—a very, very rapid rate. The x rays delivered for ankylosing spondylitis in the British series, which gives us very good figures on the carcinogenicity of radiation, were delivered at the rate of perhaps 40 rads per minute. The radiation delivered to women who had tuberculosis and were fluoroscoped to see the extent of the pneumo-thorax—the way tuberculosis was treated some 40 years ago—was at the rate of 1 or 2 rads a minute.

So, all of these data have gone into the risk calculations we have presented. They cover a range of almost 10,000 in the rate at which radiation has been delivered. Now, we do not really have very good data on radiation delivered at very much slower rates, although the uranium miner data in which the radiation was delivered at a fairly slow rate is consistent with the general [illegible] as we have about radiation carcinogenicity, complicated by the fact that the radiation was given by alpha particles from radon, and there are some ambiguities about exactly how effective this kind of high-LET radiation is compared with the usual x ray. So that introduces an uncertainty which we hope will be resolved in a few years.

Senator METZENBAUM. Would it be fair to say, though, that the impact of high-level radiation for a short duration has some comparability to the impact of low-level radiation, undefined in term, over a substantially longer period of time, but in both instances, you are going to get something similar in result?

Dr. RALL. You will get something similar but somewhat different. As I explained earlier, for x rays, there is clearly a dose rate effect. At low levels, for many cancers, it probably does not make much difference.

Senator METZENBAUM. Does your study include data with respect to the impact or the cancer incidence from low-level exposure over a lengthy period of time, or is most of your study devoted to the question of the results from the Nagasaki explosion?

Dr. RALL. There are two aspects to that question. Most of the data that we have used for these calculations come from relatively acute exposures, and the lowest have been, as I mentioned, the women with breast cancer who had fluoroscopy to their breasts for a period, perhaps once a week, for a year or so.

However, you can make calculations on people who received, say, 5 rads over the course of a year.

Senator METZENBAUM. Now, there is some new data on the atomic bomb survivor study, which I understand will be out fairly soon. Would we be better advised to withhold our conclusions with respect to your tables until that new information is made available, and its impact is cranked into your studies?

Dr. RALL. First, a comment. Two years ago, the dose recalculation on the atom bomb survivors was said to be about 1½ years away. Today, Seymour Jablon says it is about 10 months away. Once those data are available, it will then be necessary to apply them to each of the individuals affected. How long you wish to work is obviously a decision you must make. But the target date for the publication of dose recalculations, which we need to review and understand, seems to be a moving one.

Senator METZENBAUM. My last question—and Dr. Jablon, you seem to be bursting at the seams on this question. Please, respond if there is something you would like to add, sir.

Mr. JABLON. Oh, I can restrain myself. As Dr. Rall told you, we have been chasing a receding target in this dosimetry reassessment, but we have a promise on the part of both nations that we are going to have an answer by next March. But as Dr. Rall told you, it will take another year before all of the data accumulated over nearly 40 years have been reanalyzed in terms of the new dosimetry. So I would say you are looking at a time 2 years hence when we will have, presumably, new data.

But I will say this also, Senator, that the PC's will change after we have changed the risk estimates, but I would be very much surprised if they did not fall within the bars of a chart that I showed before, I think before you came in. We have allowed for uncertainty—they are uncertain—and we have tried to estimate how uncertain they are, and they are pretty wide bars, unfortunately. And we have allowed specifically for an estimate of what that reassessment is going to do.

Senator METZENBAUM. I thank you very much.

Now, Dr. Rall, with reference to my first question, I would just say, I do think that there is some question about the propriety of having a study made when it does not have some of the outside groupings and experts who do not look to the Government for either their salary or their subvention. I am sure there are such people in the country, and I think that it is not to suggest that that study made without them is tainted. But I believe that it would appear far more objective if there were people of differing points of view and people who did not have that financial relationship with the Government that I think everybody on your board of inquiry has.

Dr. RALL. I would just comment that we were concerned about that in the beginning, and that is why we asked the National Academy of Science to appoint an independent committee, chaired by Prof. Frederick Mosteller of Harvard. That committee reviewed all of our drafts and has made two of its own statements. So our committee has had the benefit of extensive review by that National Academy of Science Committee, which is generally considered not to be prejudiced.

Senator METZENBAUM. Did they pretty much concur with all of your findings?

Dr. RALL. Yes.

The CHAIRMAN. Let me add to that question, because it is going to arise. It has arisen through Senator Metzenbaum, and had he not raised it, I would have raised it, and it will rise tomorrow, again—accusations that the NIH panel and the National Academy of Sciences panel did not adequately represent the scientific community, that the panels were biased, and that their members are Government scientists who live off Government grants. Now, you have heard those accusations before. We talked about this allegation last fall. But Senator Metzenbaum has raised it, so I feel compelled to address it again, too.

This Congress depends regularly upon NIH and the Academy of Sciences for advice, and therefore, the claim that the work of these two institutions cannot be relied upon is a very, very serious charge. Let me be more specific. Why weren't Dr. John Gofman, Dr. Alice Stewart, Dr. K.Z. Morgan, or Dr. Rosalie Bertell invited to join one of the two panels? That has been, frankly, the major gripe.

Dr. RALL. For a variety of reasons, depending on the persons involved. One or two are past the age of retirement. Some of them have not published original analyses of the epidemiologic data related to radiation carcinogenesis. So it seemed inappropriate in each instance to ask them. I suppose there are many dozens of people who have widely different viewpoints on both sides who were not asked to be on the panel.

The CHAIRMAN. In other words, you are saying these are the extreme people on the antinuclear side of this matter?

Dr. RALL. Now, I must say——

The CHAIRMAN. Well, can you answer that question? Do you feel they are?

Dr. **Rall.** I cannot answer the question with respect to the National Academy of Sciences.

The **Chairman.** No. I'm not talking about these four people that I have mentioned, because you have been criticized for not——

Dr. **Rall.** The National Academy of Sciences' committee was chosen by the National Academy of Sciences and Professor Mosteller, and we had no input whatsoever into whom they chose.

The **Chairman.** Sure.

Dr. **Rall.** So they were free to choose anyone they wished, and they apparently did not ask these people to join their committee.

The **Chairman.** I see. Can we deduce from that—yes, Mr. Jablon.

Mr. **Jablon.** Senator Hatch, I cannot restrain myself. I am appalled by the suggestion that any scientist who works for the National Institutes of Health or for the National Academy of Sciences is suspected of being a crook simply because he receives money from the Government. The only possession that a scientist has which is valuable is his integrity.

Senator **Metzenbaum.** Mr. Jablon, I do not think that any of us are questioning your integrity, and I do not think anybody is suggesting that you or anyone else on the panel is a crook. I cannot take out from my thought processes the fact that Dr. John Gofman's subvention was terminated when he came up with the wrong conclusion.

I am a part of this Government. You are a part of this Government. And I am not going to say that this Government is holier than thou. It is not. And the fact is that this decision—and our chairman points out the whole issue that we call upon the National Institutes of Health, and we call upon the National Academy of Sciences, and we call upon others for opinions, oftentimes; true. But in most of those instances, we are calling upon those Government officials as impartial, objective parties. In this instance, the Federal Government's money is involved, how much we are going to be paying those claimants.

The **Chairman.** In all instances, it is involved.

Senator **Metzenbaum.** No, that is not so.

The **Chairman.** Almost all, Senator.

Senator **Metzenbaum.** When you go to the FDA and you get a decision maybe between the manufacturers of aspirin and the children, it may be with respect to any one of a number of issues. But in most instances, it is not just a question of what the Government is going to pay.

The **Chairman.** And it is not in this instance; but they are very similar.

Senator **Metzenbaum.** I do believe, and Dr. Rall, I want to say to you when you say that those men are retired, that does not mean that they do not have any mental capacity anymore. [Laughter.]

The **Chairman.** Let's have no demonstrations, or I will clear the room. We are going to show respect for everybody in this room, regardless of belief. And frankly, I do not want to hear another demonstration like that again.

Senator **Metzenbaum.** You know, I do not quite follow that comment that they are retired. Are you suggesting that some of those names that Senator Hatch mentioned are over the hill, that they no longer have any brain capacity, that they are too old to be involved? I do not think some of them are a whole lot older than some of those people sitting at the table, and I know that some of them are not older than this Senator, and he does not think that he has lost his mental capacity.

The CHAIRMAN. However, now——

Senator METZENBAUM. There are those who think so? [Laughter.]

The CHAIRMAN. I did not say that.

Dr. RALL. I have no particular comment to make about this ad hominem-type discussion. It seemed that the people on the NIH ad hoc working group were competent and expert in the field. We were delighted that the academy chose broadly from universities from the east coast to the west coast, and in their chairman had one of the most distinguished statisticians in the country. It is not possible, when there are perhaps 100 people who might be on a committee, to say why one was or was not chosen. So that I cannot quite answer your question.

Senator METZENBAUM. Mr. Chairman, it might be valuable if you and I, and perhaps others in this committee, might join together in asking the Office of Technology Assessment to give us an evaluation of these tables, and if you would be inclined to do that——

The CHAIRMAN. I do not know how you could improve upon the National Academy of Sciences, which was the independent organization to look over what these people have done.

Senator METZENBAUM. These are not really the National Academy of Sciences' tables.

The CHAIRMAN. Well, but their job was to—answer that, Dr. Rall, please.

Dr. RALL. Have you seen the National Academy of Sciences' report on the tables?

Senator METZENBAUM. I have not.

Dr. RALL. Well, the report——

The CHAIRMAN. In other words, as I understand it, we had you people come up with a report, and then the National Academy of Sciences reviewed the report—plus did their own work.

Dr. RALL. We have come up, as a matter of fact, with eight separate drafts of the report, and the Academy has seen each one except, unfortunately, their final report was based on our penultimate report. Our final report takes into consideration some of the suggestions they had about our penultimate report. But I think you will find that the reports, by and large, are in agreement.

The CHAIRMAN. I might add that the National Academy's panel will be the next panel up to testify, so they can speak for themselves. And we will ask them the same question—why weren't these four people or others, for instance, invited to join one of the two panels.

Senator Dodd, do you have any questions?

Senator DODD. No, Mr. Chairman. I think you have covered them pretty well. I have a statement that I will put in the record, but I realize time is of the essence, and I appreciate the panel being here.

The CHAIRMAN. Thank you so much.

Let me just ask one more time, and anybody on the panel can answer. The complaints I have had primarily have come down to

Dr. John Gofman, Dr. Alice Stewart, Dr. K.Z. Morgan, and Dr. Rosalie Bertell. I have had complaints on the other side, too.

In your opinions, are these people mainstream scientists? Are they people who would agree with the mainstream science community? Are they advocates? Are they wrong? Right?

Tell me what you can tell me about them, because that has been the criticism. And I think you ought to just tell us what you feel.

Dr. **Rall**. Seymour, would you like to answer that?

Mr. **Jablon**. Well, I am not too far from retirement. [Laughter.] Let me start with Dr. Rosalie Bertell. In my opinion, she is not a mainstream scientist. She is, if I recall correctly, a former teacher of mathematics in a college in upstate New York, and she was introduced to radiation studies by Dr. Irwin Bross, who was at that time at the Roswell Park Memorial Institute in Buffalo. Dr. Bross had made a very long-term investigation of leukemias that arose in the so-called tristate leukemia study. I think I can fairly say that Dr. Bross is also not a mainstream scientist. In any case, I think Dr. Bross and Dr. Bertell are on record as believing that radiation is very, very bad for you, and I do not think Dr. Bertell would claim herself to be a radiation epidemiologist.

Dr. Alice Stewart performed an invaluable service in the late fifties and sixties with the Oxford Registry of Childhood Cancers. They identified prenatal radiation as being implicated in the genesis of leukemias and of other cancers in children in their first 10 years. Subsequently, there was some dispute because there were certain discrepancies between the data that came out of the Oxford survey and the data that were coming out of Hiroshima and Nagasaki, and I think since that time, Dr. Stewart has been intent on demonstrating that the data that come out of Japan are faulty in some ways.

Dr. Gofman is a very smart guy. He knows an awful lot. He has what I might call individual views of what radiation effects are. He has written a book on the subject. He knows an awful lot. He might have been a useful member of some of these groups.

And who was the fourth person?

The **Chairman**. Dr. K.Z. Morgan.

Mr. **Jablon**. Dr. Morgan was a very eminent health physicist. He was the head of the Health Physics Division at the Oak Ridge National Laboratory—supported by the Government—for many years, and I am not aware that he has any expertise in the area of epidemiology or in cancer. In fact, his specialty was the measurement of radiation; how do you measure how much radiation somebody is receiving, not what does that radiation do for you later.

The **Chairman**. So you are saying that three of them are not in mainstream science; Dr. Gofman is a very bright guy?

Mr. **Jablon**. Yes, sir.

The **Chairman**. Is there anything that would characterize all four of them, or are they in the same category?

Mr. **Jablon**. Senator, I do not like to characterize people.

The **Chairman**. I know you do not, but the issue has been raised, and I just want to know what you feel about these people—or any of you, for that matter.

Mr. **Jablon**. I do not feel that Dr. Bertell, Dr. Stewart or Dr. Morgan would have been helpful in the task of creating the tables. I think Dr. Gofman might have been, but I cannot——

The **Chairman**. But he was not chosen.

Mr. **Jablon**. He was not—I did not choose the members.

The **Chairman**. I suspect—and I have heard the other side criticize them. Do you think that it would have been helpful to have had the people on these committees who were just totally for nuclear power, regardless of what the facts are?

Mr. **Jablon**. I do not believe so, no.

The **Chairman**. Some thought Dr. Yalow was one of those.

Mr. **Jablon**. Well, Dr. Yalow does have some extreme views.

The **Chairman**. OK. Do you feel these people have extreme views, as well?

Mr. **Jablon**. Yes, sir, I do.

The **Chairman**. Does anybody else care to comment, just so that we get this out of the way, because I have got to admit it has to be embarrassing to scientists to characterize other scientists, but I think it is important, since you have been criticized.

Dr. Beebe?

Dr. **Beebe**. I would add, Senator, only that had we represented the total spectrum of competence and opinion and attitude toward risks and toward the data, we would never have done this task in 2 years.

The **Chairman**. You would have never gotten it done.

Dr. **Beebe**. And it might not be done now.

The **Chairman**. You are saying if you got the two extremes involved, you could never bring them together.

Dr. **Beebe**. I believe that.

The **Chairman**. OK. I just thought that had to be covered, because there is no question that that is one of the criticisms, and I wanted to know how you felt.

A report by Arthur D. Little, Inc., alleges that probabilities of causation cannot be calculated, because cancer has multiple causes, and the effects of radiation cannot be sorted out.

What do you think of that idea, Dr. Rall?

Dr. **Rall**. We have discussed that in our committee and discussed it at the hearings last fall. We think they do not appreciate that we are trying to deal with conditional probability, and that we can, in point of fact, deal with these problems.

Now, it is perfectly true, as we point out, that there are many things that can cause cancer other than radiation. Probably the largest factors are unknown. And all of these factors can interact with radiation additively or multiplicatively, and can change PC calculations.

We do not feel, however, that this is a substantive criticism, nor is it a criticism that we had not considered, nor is it one which negates the concept of calculating conditional probabilities.

I think Seymour Jablon has worried over this one quite a bit and might want to a say a word.

Mr. **Jablon**. Yes, sir. When the Arthur D. Little people first made their presentation, our reply was, "But you are not taking into account the fact that we are calculating conditional probabilities." Suppose a man had radiation and then had a lung cancer, and was a cigarette smoker. We ask the question, by how much was his risk of lung cancer increased by the radiation, given that he was a cigarette smoker.

Arthur D. Little did not like that approach. We are interested exclusively in the radiation. This is not an approach, which they like or that the insurance people like. They are arguing for tagging each possible cause with its share of the total causation. Now, that is not a scientific issue, it seems to me; that is a policy issue.

The CHAIRMAN. I think that sums it up.

I understand that the tables did not apply to high-LET radiation, the kind of radiation that people are likely to inhale or ingest. How much of a problem does this represent, especially in light of the fact that there are regular allegations that doses are underestimated because investigators do not account for the isotopes people either breathe in or eat?

Dr. RALL. We do have tables for high-LET with respect to bone, although that is a special case, and high-LET with respect to radon, which would be for uranium miners. We have also described them in working level months, the ordinary way of calculating dose from radon and radon daughters to uranium miners.

This seems to take care of the larger part of high-LET radiation although one can imagine there are other examples. We felt that it was unwise to try and generalize the high-LET radiation for other tumors until a little bit more work had been done, particularly since the National Academy of Sciences has just set up a committee to study it.

The CHAIRMAN. Well, in general, what kind of a problem does dosimetry represent?

Dr. RALL. A large problem. It depends on what you are talking about, however.

The CHAIRMAN. Well, I am talking about situations in which dose estimates are likely to be particularly difficult. I am talking, really, about the nuclear fallout cases from atmospheric tests.

Dr. RALL. The dose from fallout is difficult to calculate. There is a study under way, trying to reevaluate all that.

However, for nuclear power workers, the dose estimates are really quite good, because they are badged.

The CHAIRMAN. Now, the law requires that the tables report should be regularly updated. What is the Department of Health and Human Services doing to plan for this update, and really, after having gone through this experience, how do you feel this update should take place, or how should it be organized?

Dr. RALL. In my opinion, the Department of Health and Human Services should appoint a committee fairly promptly and should have liaison with the National Academy of Sciences' committee on the high-LET problem, and should have liaison with the Japanese recalculations and dose assessments. As we have been saying, in 1½ to 2 years time, more data will be available, and by that time, the committee can get its teeth into getting the work done, so that a report can come out perhaps 3 years from now.

The CHAIRMAN. Now, the report, it seems to me, can be used in two ways. The tables can be taken as is, as representing best estimates, or the report can be used in a fuller sense.

In other words, the discussions and estimates of the uncertainties can figure in the actual judgments. How do you feel the report ought to be used?

Dr. **Rall**. The present report?

The **Chairman**. Right.

Dr. **Rall**. I think you should use it first by calculating the PC and then by examining carefully the problems associated with that particular cancer and finally by analyzing the uncertainties involved. The 90-percent credibility levels which you can calculate for each PC should be an integral part of the use of the tables.

The **Chairman**. Well, do you think that the NIH report represents an improvement over BEIR-III for the purposes of assessing radiogenic cancer claims?

Dr. **Rall**. BEIR-III had a slightly different objective, because they were not trying directly to calculate probability of causation. So that the objective was different. But in addition, we had considerably more evidence available than BEIR-III did because the Japanese data, for example, available to BEIR-III, I think, concluded in 1974, and we have had data through 1980 from the Japanese experience. So we have had considerably more data available.

The **Chairman**. Do any of you others have any final comments you would care to make to the committee today?

Dr. Beebe.

Dr. **Beebe**. Mr. Chairman, I would just like to read a couple of sentences from chapter 8, which has to do with the future revision of the tables, because it expresses a personal view of my own. It says:

> The tables cannot now provide precise measures of the probability that certain cancers have resulted from previous exposures to known doses of ionizing radiation. The tables do represent; however, a first and important step in the direction of a rational basis for assigning to radiation exposure a measure of the likelihood of its role in the causation of individual cancers.

I think it is an important first step. How useful it would be, I think, depends on others.

The **Chairman**. Well, thank you.

Any other comments?

[No response.]

The **Chairman**. Well, I just want to thank you all for being here today. We gave you an hour to present, and you took about an hour, and then we took about an hour for questions. But I am very grateful to you for being here, the effort that you have put forth, and I think you have been very candid, Dr. Rall—well, all of you have, certainly—Mr. Jablon, you have been very candid, and I think that it has been very helpful.

Mr. **Jablon**. Well, I am the oldest one here.

The **Chairman**. I think it has been very helpful to the committee, and I want to congratulate you on the amount of effort you have put forth and the work that you have done and the testimony you have given to us today. I think it has been very helpful in many ways.

So, thank you so much, and just keep the committee informed as we continue to work on these matters. Thank you for being with us.

The CHAIRMAN. I should have known we are not going to be able to finish this morning.

Our second panel happens to be two representatives of the special National Academy of Sciences Committee that was established to review and critique the work of the NIH panel. The Academy's Oversight Committee on Radioepidemiological Tables developed a report that is almost as long as the NIH report. This committee has also worked hard and provided an important contribution to this effort. I am pleased to welcome Dr. Frederick Mosteller, who was chairman of the committee, and Dr. Eugene Saenger.

Dr. Saenger, it is good to see you again. I think I met you in Philadelphia last year. And also, we have Dr. Steve Brown, as I understand it, with us here today.

So, Dr. Mosteller, we will turn to you and ask you to make your presentation.

STATEMENT OF DR. FREDERICK MOSTELLER, CHAIRMAN, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT, HARVARD UNIVERSITY SCHOOL OF PUBLIC HEALTH, AND CHAIRMAN, OVERSIGHT COMMITTEE ON RADIOEPIDEMIOLOGIC TABLES; AND DR. EUGENE SAENGER, UNIVERSITY OF CINCINNATI MEDICAL CENTER, CINCINNATI, OH, ACCOMPANIED BY DR. STEPHEN BROWN, STAFF OFFICER FOR OVERSIGHT COMMITTEE

Dr. MOSTELLER. Mr. Chairman, thank you for inviting me to testify about the radioepidemiological tables and related matters.

My name is Frederick Mosteller, and I am a professor of mathematical statistics at Harvard University, and chairman of the Department of Health Policy and Management at Harvard's School of Public Health. From August 1983 until January 1985, I chaired the Oversight Committee on Radioepidemiological Tables.

At the request of the Assistant Secretary for Health, that committee was formed by the National Research Council. Our committee was asked to provide a peer review of the work of the ad hoc working group, who have just testified.

Most of my testimony is based on the work of the oversight committee, but I may identify some points as my own statements.

My eight distinguished colleagues on the oversight committee made the work possible. Dr. Saenger, with me today, will also testify. Dr. Stephen Brown, staff officer for the committee, on my left, is here to assist with questions.

Mr. Chairman, let me begin with some general remarks about radiation cancer. That increased radiation causes excess cancer is well established. Our medical colleagues assure us, however, that with present knowledge, one can rarely distinguish a radiation-related cancer from one arising in the absence of radiation. Thus, any method for adjudicating claims for radiation-related cancer will ultimately use arguments regarding the probabilities that the cancer in question was related to a specific prior dose of radiation, or the share of causation that dose might bear.

It seems desirable to have scientific assessment of these probabilities. I personally am pleased that the Congress is considering the usefulness of such an assessment. The tables could be used both for future compensation plans and for those engaged in current tort law deliberations.

Now let me turn to the radioepidemiologic tables and numbers that appear in them. The idea behind the radioepidemiologic tables is that one can estimate the probability that a specified dose of radiation caused a specific cancer, given knowledge about the radiation, the type of cancer, and various characteristics of the cancer victim.

The probabilities being calculated must be based on a limited set of characteristics of the individual. The probability depends on the set chosen. Different sets of characteristics give different probabilities of causation for the same person. We must have substantial data to make it possible to compute the estimates; thus, we use only those characteristics to place a person in a group about which we can know or can estimate cancer rates with and without exposure to radiation.

The definition of these groups is only partly a scientific matter. Social considerations also apply. Moreover, radiation may not be the only cause of the cancer. The calculations provide an estimate of the share that might be assigned to the dose or radiation. The charge of the oversight committee was to evaluate the data, assumptions, methods and means of handling uncertainties used by the working group in devising the tables. The task of creating tables for available information is replete with technical difficulties and uncertainties, as Drs. Rall, Land, and Jablon's testimonies show. The ad hoc working group is to be congratulated for undertaking and completing the first set of tables. The data on radiation and cancer are too sparse by themselves to support the requested tables, and therefore, assumptions must be made in order to carry out the calculations.

Among the difficulties facing the working group were choosing and fitting the models, using animal and laboratory data, extrapolating from high to low dose, relating age at exposure to age of diagnosis, handling other risk factors, and choosing sources of data. Given these issues, any specific estimates of probabilities or shares can be substantially uncertain, even if the characteristics of the cancer victims and their radiation exposures are well known.

Other methods for evaluating claims will also be subject to uncertainty, because they would have to take the information in the tables into account, as well as other matters. We have not examined an analysis of uncertainties by other methods.

Although the oversight committee was not specifically asked by the Assistant Secretary for Health to do so, it decided to discuss selected wider issues regarding the use of the tables. First, it noted that the uncertainties in the tables, because they could be easily identified by the parties to a dispute, might reduce the usefulness of the tables for compensation decisions.

Changes in the tables, some of which can already be anticipated—especially those arising from the revision of the Japanese dosimetry—might cast doubts about the credibility of the tables if they are pressed into service without a suitable plan for later adjustment.

Second, the uncertainties in the tables may well cause other difficulties if the compensation formula to be used with them contains discontinuity.

Third, the tables may not apply to certain types of claims; for example, with respect to medical radiation, where the population at risk is different from the general population for which the tables were constructed. And of course, the social context is different. The radiation is applied deliberately for the presumed benefit of the patient. My colleague, Dr. Saenger, may have more to say on this subject.

Finally, the tables imply decisions about the nature and magnitude of the risk factors for cancer that apply to radiation under specified conditions. If the assumptions about these risk factors are not the same as those used in setting radiation protection guidelines, difficulties may arise, as you have already discussed earlier today.

From the above observations, it is possible to draw several conclusions. First, the tables can provide a valuable tool in analyzing the relationship of cancer and radiation, where the ordinary ideas of causation are difficult to apply. The current version of the tables required the use of uncertain data and assumptions. Some of the resulting uncertainties in the probabilities or the shares can be removed in a relatively few years by further research, but some may remain indefinitely. Consequently, caution is advisable in putting the tables to use. The congressional mandate to revise the tables periodically was wise. As in previous proposals before this committee to use the tables for compensation decisions; it is also wise to provide a mechanism for reconsidering specific decisions should the tables change.

Mr. Chairman, thank you for allowing me the opportunity to present these thoughts. I will be happy to answer questions now, or after the testimony by Dr. Saenger.

The CHAIRMAN. Thank you, Dr. Mosteller.

[The prepared statement of Dr. Mosteller and responses to questions submitted by Senators Kerry, Simpson, and Grassley follow:]

TESTIMONY OF FREDERICK MOSTELLER
REGARDING THE RADIOEPIDEMIOLOGIC TABLES

Senate Committee on Labor and Human Resources
June 11, 1985

Mr. Chairman, thank you for inviting me to testify regarding the radioepidemiologic tables and related matters. My name is Frederick Mosteller. I am Professor of Mathematical Statistics at Harvard University and Chairman of the Department of Health Policy and Management at Harvard's School of Public Health. From August 1983 until January 1985, I served as Chairman of the Oversight Committee on the Radioepidemiologic Tables. That Committee was formed by the National Research Council at the request of the Assistant Secretary for Health. It was asked to provide a peer review of the work of the Ad Hoc Working Group, from which you have just heard. Most of my testimony is based directly on the findings of the Committee's report; however I may identify some points as my own statements.

I wish first to acknowledge the contributions of my eight distinguished colleagues on the Oversight Committee. Dr. Eugene Saenger is here with me today and will also testify; Dr. Stephen Brown, Staff Officer for the Committee, is also here to assist with questions.

Mr. Chairman, I want to begin with some general remarks about radiation and cancer. That increased radiation causes excess cancer is well established. Our medical colleagues assure us, however, that one can rarely distinguish a radiation-related cancer from one arising in the absence of radiation. Consequently, any method for adjudicating claims for radiation-related cancer will ultimately use arguments regarding the probabilities that the cancer in question was related to a specific prior dose of radiation or regarding the share of causation that the dose should bear. It seems desirable to have a scientific assessment of these probabilities. I am glad Congress is considering the possibility that such an assessment might be useful. The tables could be useful for future compensation plans and to those engaged in current tort law deliberations.

Now let me turn to the radioepidemiologic tables and the numbers that appear in them. The idea behind the radioepidemiologic tables is that one can estimate the probability that a specific dose of radiation caused a specific cancer, given knowledge about the radiation, the type of cancer, and various characteristics of the cancer victim. The probablilities being calculated must be based on a limited set of characteristics of the individual. We must have substantial data to make it possible to compute these estimates. Thus we use only those characteristics that place a person in a group about which we know or can estimate cancer rates with and without exposure to radiation. The definition of these groups (or what in statistics we call a partition) is only partly a scientific matter; social considerations also apply. Moreover, radiation may not be mutually exclusive of other possible causes of cancer. The calculations provide an estimate of the share that might be assigned to the dose of radiation.

The charge of the Oversight Committee was to evaluate the data, assumptions, methods, and means of handling uncertainties used by the Working Group in devising the radioepidemiologic tables. The task of creating radioepidemiologic tables from available information is replete with technical difficulties and uncertainties. The Ad Hoc Working Group is to be congratulated for undertaking and completing the first set of tables. The data on radiation and cancer are too sparse by themselves to support the requested tables, and therefore assumptions must be made in order to carry out the calculations. Among the difficulties facing the Working Group were:

o Deciding on the methods to use to analyze the available information on cancer in human populations exposed to radiation.

- Deciding on how to use information on radiation and cancer obtained in laboratory experiments with animals or cell cultures.

- Extrapolating from high to low doses of radiation.

- Determining the influence of age at exposure to radiation and time from exposure to diagnosis of the cancer.

- Deciding how to treat risk factors for cancer other than radiation.

- Deciding which sources of information on baseline cancer rates and radiation-related excess cancer to use.

Given these difficulties, any specific estimates of probabilities (or shares) can be substantially uncertain, even if the characteristics of the cancer victims and their radiation exposures are well known. These uncertainties, discussed by the Working Group in its report, need to be acknowledged and taken into account if the tables are to be used for compensation decisions. Other methods for evaluating claims will also be subject to uncertainty, because they would have to take the information in the tables into account as well as other factors. We have not examined any analysis of the uncertainties in other methods.

Although the Oversight Committee was not specifically asked by the Assistant Secretary for Health to do so, it decided to analyze selected wider issues regarding the use of the tables. First, it noted that the uncertainties in the tables, because they could be easily identified by the parties to a dispute, might reduce the usefulness of the tables for compensation decisions. Changes in the tables, some of which can already be anticipated, might cast doubts about the credibility of the tables if they are pressed into service without a suitable plan for later adjustments. Second, the uncertainties in the tables will cause even more difficulties if the compensation formula to be used with them contains discontinuities. Third, the tables may not apply to certain types of claims, for example with respect to medical radiation, where the population at risk is different from the general population for which the tables were constructed. And even if the numbers in the tables were scientifically applicable to claims for medical irradiation, the social context is different; the radiation is applied deliberately for the presumed benefit of the patient. My colleague, Dr. Saenger, may have more to say on this subject. Finally, the tables imply decisions about the nature and magnitude of the risk factors for cancer that apply to radiation under specified conditions. If the assumptions about these risk factors are not the same as those used in setting radiation protection guidelines, difficulties may arise.

From the above observations, it is possible to draw several conclusions. First and foremost, the radioepidemiologic tables can in principle provide a valuable tool in analyzing the relationship of cancer and radiation, where the ordinary ideas of causation are difficult to apply. The current version of the tables required the use of uncertain data and assumptions. Some of the resulting uncertainties in the probabilities (or shares) can be removed in a relatively few years by further research, but some will remain indefinitely. Consequently, caution is advisable in putting the tables to use.

The congressional mandate to revise the tables periodically was wise. As in previous proposals before this Committee to use the tables for compensation decisions, it is also wise to provide a mechanism for reconsidering specific decisions should the tables change.

Mr. Chairman, thank you for allowing me the opportunity to present these thoughts. I will be happy to answer questions now or after the testimony by Dr. Saenger.

From Senator John Kerry
(On HHS Radiation Tables)

For Dr. Frederick Mosteller:

1. In its report, the Academy Oversight Committee stated that the Working Group "...does not present much quantitative information about uncertainties and does not quantify their influence on the reliability of the assigned shares in the tables." The Committee recommended a quantitative appraisal of uncertainties, perhaps in the form of a sensitivity analysis. Do you feel the Working Group adequately satisfied this recommendation in its final report? Please state the reasons for your answer.

2. On page 10 of its report, the Oversight Committee indicated it believes that a delay in mandating application of the tables should be considered until uncertainties are substantially reduced by use of new data and methods. In addition to the reassessment of the radiation dosimetry and cancer incidence in the Hiroshima and Nagasaki populations, are there other uncertainties to which this statement applies? What criteria would you use to determine that the uncertainties had been "substantially reduced"?

Answers to questions from Senator John Kerry
to Frederick Mosteller

1. Concerning uncertainties.

At the time that the Academy Oversight Committee was required to write its final report, the Working Group had not prepared its treatment of uncertainties. In its final report, the Working Group gives an adequate treatment of uncertainty, in my opinion. The Working Group calls these uncertainties Credibility Limits rather than Confidence Limits because special assumptions are required to compute them. However, these have been provided in such a way that others wishing to make different assumptions can recalculate the limits. In its final report the Working Group provided an extensive chapter that reviews each source of uncertainty and assesses numerically the impact of these uncertainties in the numbers in the tables, and finally assembles the components in a suitable way. They provide tables to assist in the calculations.

2. Issue of delay and reduction of uncertainty.

An important issue was that if the tables needed to be redone immediately after being put in use, then unless some plan were made to redress changes resulting from the reasssessment of the Japanese data the tables would lose credibility. The possibility was also available that in a new analysis other methods of fitting the data might reduce uncertainty, and further down the road, perhaps the next BEIR report (just getting started) might also provide less uncertainty especially for internal emitters and alpha radiation. (Relevant for Uranium miners.) To tell how much uncertainity had been reduced, one could recompute the credibility limits as provided in the Working Group's report.

It is my personal opinion that once the reassessment of the Japanese data has been completed and adjusted for in the tables, little further reduction in uncertainty will occur in a period such as 5 years. One purpose of the Academy Oversight Committee in recommending a Standing Committee on the tables was to make sure that opportunities to improve the tables would be grasped in timely manner with time for implementation.

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD

FOR DR. FREDERICK MOSTELLER, CHAIRMAN, OVERSIGHT COMMITTEE

1. In your Oversight Committee report--which came out prior to publication of the Ad Hoc Working Group's final report--you have discussed the various uncertainties associated with the "probability of causation" tables and, on page 8 of the report, you make the following statement: "Considering all sources of uncertainty, the estimated assigned shares could often be substantially in error." Would you please expand upon that statement and, in addition, give us your view of this issue, based upon your evaluation of the Ad Hoc Working Group's final report?

2. Are the uncertainties that you have identified in the current probability of causation report of sufficient magnitude to warrant additional scientific work, prior to using these tables as a basis for compensating individual cancer claimants, or do the tables have a sufficient degree of accuracy now to be able to apply them in this context? In this regard, would you expand on your statement that "a delay in mandating their application should be considered, until such uncertainties are substantially reduced by use of new data and methods"?

3. In Chapter II of your Oversight Committee report, you point out that the expression "probability of causation" implies a "simplistic view of causation--a single source of exclusive cause--that does not agree with the evidence." What do you mean by that statement, and what significance does that statement, if true, have on attempting to assign a share of the cause of an individual's cancer to radiation exposure?

4. You also note, in the same chapter, that the term "probability of causation" "suggests that it applies to individuals, whereas in fact it is a property of a group that is assigned to all the people in the group." Given that, is it then possible to use this methodology as a basis for compensating an individual who claims that his cancer was caused by exposure to radiation?

5. Would you comment on your view of the potential impact of this methodology, if employed as a basis for compensation, on the way in which occupational radiation protection standards are established in this country? Would a decision to compensate an individual for a given level of radiation exposure serve to undermine the approach that we have taken to radiation protection standards, where the Federal government may, indeed, have determined that such a dose is permissible?

Answers to questions from Senator Alan K. Simpson
to Frederick Mosteller

1. Uncertainties and error.

It is the nature of this problem that the many assumptions required and the uncertainties in the data will leave substantial uncertainties in the final estimates. These are considered in Chapter VII of the Working Group's Report. As mentioned in my response to Senator Kerry's question, the Working Group has provided a way of assessing uncertainty and also a way to assess it differently if one wishes to make somewhat different assumptions.

2. Reduction in uncertainties.

Please also see my response to Senator Kerry's second question. As suggested there, the revision of the tables in the light of the reassessment of the Japanese dosimetry seems desirable. This could, of course, be accomplished by making provision for changing values of the table in advance of their use.

Different people will have different views about whether the tables are sufficiently accurate for use. My own view is that they are the strongest information we have on the subject at this time, and I regard the assessment of the uncertainty as a benefit rather than a loss. An important issue is just how the tables might be used. Does one use them directly and compute an award from a function relating the probability of causation to the award? Or should additional information be supplied and adjustments made in the light of this? (Adding information is very difficult because the background data are not likely to be available, and because the effect of additional data on the probability of causation is often counterintuitive.) Or should the uncertainties in the tables be used as part of thinking about the award?

It seems to me that once we recall that awards are being made regularly without these tables and without any quantitative assessment of uncertainties, the award system is considerably advanced by the presence of the tables and their information about uncertainties.

3. Meaning of probability of causation.

If we had a group of 100 people who had cancers of a certain kind, and 20 had been caused by a dose of radiation, and the rest had not been so caused, then we might say that probability of the radiation causing the cancer is 0.2 because a random person drawn from the group would have had their cancer caused by the radiation. If, however, cancers are caused jointly both by the radiation and by other things as well, so that all we can say about 100 cancers is that there are 20 more of them than have occurred in a comparable group of unexposed people, then we can't say that some people had their cancer caused by the radiation and others did not. Instead, we would have merely an added risk all told. We cannot ordinarily tell whether the cancer is caused by radiation let alone by the specific dose radiation. In spite of this, we can speak of the increase being 0.2 or 20 per cent, and it seems to me reasonable to think of the tables as useful for the purpose intended. I do not see this as a drawback, but as a strength.

4. Group property of probability of causation.

I see no reason why the group property of probability of causation should prevent its use for compensation. Such ideas are used regularly in insurance. I do think it important to understand the idea because the choice of the variables for producing groups is a complicated one depending on science, practicality, the legislation, and ultimately the courts. A person has a different probability of causation for every group he or she belongs to. Therefore, the choice of the variables for describing the groups matters. Science can sometimes tell whether a variable matters and how much. It is a practical question what variables we can get data for. It is a legislative question which variables enter the law. And the courts can overrule the use of some variables as they did in the case of sex in computing annuity payments. Society is free to ignore information if it wishes, and to act even if it does not have all the information it would like. Once the rules are set out they can be applied.

5. Radiation compensation and safety standards.

I am not an expert in this field.

Occupational safety standards are set up prospectively to keep the probability of disease low. They cannot guarantee total protection. The probability of causation approach is retrospective -- it recognizes that an undesirable outcome has occurred and offers a way to help compensate for it. It is conceivable (though I am not sure how likely) that someone getting a cancer who worked in a radiation environment might even when properly protected turn out to have a claim under a probability of causation approach.

If the purposes of the two approaches are kept in mind, there should be no conflict. We would recognize, of course, that we still would not know whether the cancer was caused by the radiation experience.

From Senator Grassley

QUESTIONS FOR RADIOEPIDEMIOLOGICAL TABLES HEARING

FOR PANEL TWO: DR. MOSTELLER

DO YOU CONSIDER THE ANALYSIS PROVIDED BY THE AD HOC WORKING GROUPS TO BE THE BEST AVAILABLE TOOL FOR ESTIMATING THE PROBABILITY THAT PARTICULAR CANCERS IN PARTICULAR INDIVIDUALS WERE CAUSED BY RADIATION EXPOSURE?

IT HAS BEEN SUGGESTED THAT, BECAUSE THE MEMBERSHIP OF THE AD HOC WORKING GROUP CONSISTED LARGELY OF GOVERNMENT SCIENTISTS, THE APPEARANCE OF A LACK OF OBJECTIVITY IS CREATED, AND, BEYOND THAT, THAT THE ANALYSIS MIGHT NOT HAVE BEEN DONE IN AN OBJECTIVE FASHION.

CAN YOU COMMENT?

Answers to question from Senator Grassley
to Frederick Mosteller

1. Estimating the probability that particular cancers were caused by radiation exposure in particular individuals.

I do regard the tables as the best available tool for estimating the probabilities. Even though the question asks about specific individuals and statistics can be given only for groups, I think this is the best that can be done. If Congress wished additional variables to be considered in the stratification, they could ask for them, though it may be difficult or impossible to get the data.

2. Issue of membership of the Working Group.

Although the membership of the Working Group was drawn largely from scientists in government service, this seems almost inevitable to me because the task requires such familiarity with atomic bomb and other cancer data and scientific information about cancer and statistics. As I recall, the meetings of the Working Group were open, and so I would have thought that issues of bias would quickly have been made public.

In the deliberations of the Working Group and those of the Academy Oversight Committee I heard many disagreements, but I have not heard criticism that bias occurred because of membership in a group. I do understand the issue of the need for appearance of fairness as well as that of being fair. All I can say is that the American people were very fortunate to have had such an outstanding group of scientists as those in the Working Group preparing these tables.

The **Chairman**. We will turn to you, Dr. Saenger, and if you could summarize, I would appreciate it, because I am running out of time, and we will have some questions for both of you.

Dr. **Saenger**. Senator Hatch, thank you for the privilege of being able to appear before you. I want to address only one specific issue in this whole discussion of radioepidemiologic tables—namely, the effect of the tables as they might be applied to the practice of medicine where radiation is used in the healing arts.

A major concern in the development of these tables was their potential effect on the practice of medicine, particularly the effect on radiation therapy for cancer, the diagnostic application of x rays, and the uses of nuclear medicine in diagnosis and therapy. The attitude of the oversight committee was summed in a statement as follows, from the report:

> Another example would be radiation recieved in connection with medical diagnosis or treatment. The committee notes that medically exposed populations are different—sometimes greatly different—- from the general population and that the values of assigned shares calculated for an unselected population would not generally apply to cancers, especially second cancers, in medically exposed persons. In addition, because medical radiation is used for therapy and diagnosis, compensation in these circumstances may be judged inappropriate for social reasons.

In chapter VII discussing "Wider Issues" this subject is addressed in greater detail in stating:

> The Oversight Committee notes that tables created for the specific types of claims against the government may not apply, in a scientific sense, to other types of claims. The current tables are designed to apply to a claimant drawn from the general population, whereas a person who is irradiated medically is different from a random member of the general population, because of the medical circumstances that led to his or her irradiation. The clearest example is the development of a second primary cancer in a person who received radiotherapy for a first cancer. Such differences may mean that an assigned share calculated for a person of the same sex, age at exposure, and age at diagnosis and with the same dose may not be appropriate for the person who received medical radiation.

I will skip one other paragraph which is in the report, because of time constraints.

In order that a well-defined data base is supplied to substantiate the points developed here, the committee developed appendix H—a copy attached to my testimony—which details a number of scientific papers from the referred literature to illustrate the dilemma that could be faced as a consequence of excellent medical care.

Thank you.

[The prepared statement of Dr. Saenger follows:]

Possible Medical Consequences Arising from the Use of the Radioepidemiological Tables

Submitted by
Eugene L. Saenger, M.D.
University of Cincinnati Medical Center
Cincinnati, Ohio

A major concern in the developement of the radioepidemiological tables was their potential effect on the practice of medicine - particularly the effect on radiation therapy for cancer, the diagnostic applications of x-rays and the uses of nuclear medicine in diagnosis and therapy. In the Executive Summary of the report, "Assigned Share for Radiation as a Cause of Cancer" of the Oversight Committee on Radioepidemiologic Tables, the Committee states as follows:

> "Another example would be radiation received in connection with medical diagnosis or treatment. The Committee notes that medically exposed populations are different (sometimes greatly different) from the general population and that the values of assigned shares calculated for an unselected population would not generally apply to cancers - especially second cancers - in medically exposed persons. In addition, because medical radiation is used for therapy and diagnosis, compensation in these circumstances may be judged inappropriate for social reasons."

In Chapter VII discussing "Wider Issues" under the heading of "B. Applicability of Tables", the Committee addresses the subject of medical irradiation further as follows:

> "The Oversight Committee notes that tables created for the specified types of claims against the government may not apply, in a scientific sense, to other types of claims. The current tables are designed to apply to a claimant drawn from the general population, whereas a person who is irradiated medically is different from a random member of

the general population, because of the medical circumstances that led to his or her irradiation. The clearest example is the development of a second primary cancer in a person who received radiotherapy for a first cancer (see Appendix H). Such differences may mean that an assigned share calculated for a person of the same sex, age at exposure, and age at diagnosis and with the same dose may not be appropriate for the person who received medical radiation.

"Other differences between the uses specified in S.921 and broader ones include whether the irradiation was intended to be beneficial (as in medical radiation) and whether it was within accepted standards for radiation protection (e.g., for occupational exposures). For these reasons, Congress may wish to be specific about the applicability of the tables of assigned shares to classes of people other than those specified in S.921."

In order that a well defined data base is supplied to substantiate the points developed above, the Committee developed Appendix H (copy attached) which details a number of scientific papers from the refereed literature to illustrate the dilemma that could be faced as a consequence of excellent medical care.

Respectfully submitted,

Eugene L. Saenger, M.D.

Eugene L. Saenger, M.D.

ELS/sck

enclosures

E.L. Saenger, M.D.

APPENDIX H

ASSIGNED SHARE AND MEDICAL PRACTICE

A second primary cancer of the same or different histologic type may occur some years after the apparently successful radiation treatment of an earlier cancer.[1] In considering the likelihood that therapeutic radiation would be followed by the appearance of a second cancer some years later, could the treating physician be considered liable for inducing the second neoplasm if a nonzero assigned share could be calculated?

Persons undergoing therapeutic radiation have an increased incidence of later neoplasms, most often in or near the sites of the irradiated lesions.[5,7,10-12] The papers just cited could be interpreted as suggesting that medical radiation is causative. Tables I-1 and I-2, from Boice,[1] indicate populations studied for later neoplasms after radiation therapy for benign and malignant diseases.

There are also reports of increases in carcinogenic effects due to medical diagnostic radiation exposure. The use of thorium dioxide (thorotrast) as a contrast agent in radiographic procedures between 1930 and 1955 has led to excess mortality from liver cancer and acute leukemia. Women who received multiple chest fluoroscopic examinations to monitor pneumothorax treatment for pulmonary tuberculosis are at increased risk of breast cancer. Apart from these examples, however, epidemiologic studies of medical diagnostic radiation exposures and of the use of diagnostic radionuclides, such as iodine-131, have generally not demonstrated an increased risk of leukemia or other forms of cancer in exposed patient populations.[2,3,8,9]

The use of adjuvant chemotherapy for cancer, with or without radiation therapy, as in the treatment of patients with Hodgkin's disease and the non-Hodgkin's lymphomas, has been associated with an increased risk of acute nonlymphocytic leukemia.[4,6] These reports

TABLE I-1

Studies of Populations Irradiated for Benign Disease[a]

Treatment for	Excess Cancers
Ankylosing spondylitis	Leukemia, lymphoma, lung, pharnyx, stomach, pancreas, bone, others
Postpartum mastitis	Breast
Thymus hypertrophy	Thyroid
Tinea capitis	Thyroid, brain
Benign head and neck disease	Thyroid
Metropathia hemorrhagica	Leukemia, intestine, rectum, uterus

---

[a] Reprinted with permission from Boice.[1]

TABLE I-2

Studies of Populations Irradiated for Malignant Disease[a]

Treatment for	Excess Cancers
Cervical cancer	No leukemia, possibly bladder, rectum, uterus
Childhood cancer	Other cancers or sarcomas
Hodgkin's disease	Leukemia, non-Hodgkin's lymphoma
Ewing's sarcoma	Osteosarcoma
Retinoblastoma	Osteosarcoma
Ovarian cancer	Bladder, colon

---

[a] Reprinted with permission from Boice.[1]

indicated that chemotherapeutic agents, particularly alkylating agents, appear to have a greater leukemogenic potential than radiation.

Many of the irradiated populations would not have the same baseline cancer rates as the general population, even if one discounted their primary cancer; they often have an increased risk of a second cancer. Patients whose radiation exposure is diagnostic, rather than therapeutic, are also different from the general population to some degree. Thus, in many instances of medical radiation, tables of assigned shares based on radiation risk factors and baseline rates in the general population would not apply to the irradiated population, because of selection factors other than radiation.

REFERENCES

1. Boice, J. D. Cancer following medical irradiation. Cancer 47:1081-1090, 1981.
2. Boice, J. D., Jr., C. E. Land, R. E. Shore, K. E. Norman, and M. Tokunga. Risk of breast cancer following low-dose radiation exposure. Radiology 131:589-597, 1979.
3. Boice, J. D., and R. R. Monson. Breast cancer in women after repeated fluoroscopic examinations of the chest. JNCI 59:823-632, 1977.
4. Boivin, J.-F., and G. Hutchinson. Second cancers after treatment for Hodgkin's disease. A review, pp. 181-197. In J. D. Boice, Jr., and J. F. Fraumeni, Jr., Eds. Radiation Carcinogenesis. Epidemiology and Biological Significance. New York, N.Y.: Raven Press, 1984. 489 pp.
5. Gomori, J. M., and A. Shaked. Radiation induced meningiomas. Neuroradiology 23:211-212, 1982.
6. Green, M. H. Interaction between radiotherapy and chemotherapy in human leukemogenesis, pp. 199-210. In J. D. Boice, Jr., and J. F. Fraumeni, Jr., Eds. Radiation Carcinogenesis. Epidemiology and Biological Significance. New York, N.Y.: Raven Press, 1984. 489 pp.
7. Kleinerman, R. A., R. E. Curtis, J. D. Boice, Jr., J. T. Flannery, and J. F. Fraumeni, Jr. Second cancers following radiotherapy for cervical cancer. JNCI 69:1027-1033, 1982.
8. Land, C. E., J. D. Boice, Jr., R. E. Shore, J. E. Norman, and M. Tokunaga. Breast cancer risk from low-dose exposures to ionizing radiation. Results of parallel analysis of three exposed populations of women. JNCI 65:353-376, 1980.
9. Pillary, R., J. Graham-Pole, R. Miraldi, B. Yulish, A. Newman, and J. Liebman. Diagnostic x-irradiation as a possible etiologic agent in thyroid neoplasms of childhood. J. Pediat. 101:566-568, 1982.

10. Pretorius, H. T., M. K. Katikineni, T. J. Kinsella, S. H. Barsky, M. F. Brennan, E. W. Chu, and J. Robbins. Thyroid nodules after high-dose external radiotherapy. J. Am. Med. Assoc. 247:3217-3220, 1982.

11. Sandler, D. P., G. W. Comstock, and G. M. Matanoski. Neoplasms following childhood radium irradiation of the nasopharynx. JNCI 68:3-8, 1982.

12. Smith, P. G., and R. Doll. Mortality among patients with ankylosing spondylitis after a single treatment course with x-rays. Br. Med. J. 284:449-460, 1982.

The CHAIRMAN. Thank you so much.

I might as well start right off with the question I asked the last panel, about why, Dr. Mosteller, you did not pick any of those four people or others who believe the same way they do.

Dr. MOSTELLER. I am afraid, Senator, you will have to ask somebody else. I did not pick any of the people. I can only say that part of the reason for picking me was that I had no position on cancer and radiation at all, and no previous publications in this field.

The CHAIRMAN. So you were completely neutral on the issue?

Dr. MOSTELLER. Yes.

The CHAIRMAN. Do any of you——

Dr. MOSETLLER. I have nothing to say about these people, nor would I be competent even to comment on their strengths or weaknesses.

The CHAIRMAN. OK.

Dr. Saenger.

Dr. SAENGER. Well, Dr. Rosalie Bertell, I do not know her personally at all. I have had no contact with her. In regard to Dr. Morgan and Dr. Gofman, I have known both of these gentlemen over the years. I must say that our viewpoints differ considerably, and particularly on the subject matter which comprises the basis of the radioepidemiological tables. I have been the author of a number of radioepidemiological investigations concerned with carcinoma of the thyroid. There have been a number of papers from the laboratory that I direct. These have all been published in the referred literature. I also have chaired a report on the question of leukemia following radio-iodine therapy for hyperthyroidism, which is widely quoted in the referred medical literature.

I think that the reason, perhaps—and again, I had nothing to do with the choosing of these several individuals in the Academy committee, nor did I have anything to do with my own choice—may stem from the fact that although their opinions have been very widely-quoted, and I think these are matters of individual interpretation, that they do not represent what is meant when we say that a publication has been made in the referred medical literature.

The CHAIRMAN. OK. Dr. Mosteller, did your panel have any differences with the NIH panel that were not resolved in the final NIH report?

Dr. MOSTELLER. I imagine that there are small ones, but no major ones.

The CHAIRMAN. All right. Generally, do you believe that the NIH report represents the best available science and scientific expertise as was required by the law that I passed, or do you think that the NIH panel was biased in any way?

Dr. MOSTELLER. I have no reason to think that they were biased. I attended some of their meetings, and they were hot and heavy. The extreme positions, I think, were represented at every meeting.

The CHAIRMAN. In other words, on both ends of the spectrum, both pro-nuclear and anti-nuclear?

Dr. MOSTELLER. Yes, indeed. I thought that the discussions were vigorous, just as the discussions of the oversight committee were very vigorous. So that I am very comfortable about the quality of the work that was performed and pleased with the responsiveness of the working group to many, many suggestions from our committee which must have been irritating to them when they had so much to do. They adopted a great many of our suggestions, and the ones that they adopted in the final report went a very long way to accomplishing what we hoped they would be able to accomplish, and together with us, they summarized in the back of their report what they think would be a good long run plan if the tables are to continue.

The CHAIRMAN. Do you then think that this NIH report, with the suggestions incorporated therein and the work that has been done is really the best available science and scientific expertise, as required by our law?

Dr. MOSTELLER. Well, I suppose when you drive a scientist up against "best", expecially a statistician, where that is a technical word for him, it creates a problem.

Let me just say, I thought it was a first class job, a first class job.

The CHAIRMAN. Dr. Mosteller, you are an expert on the application of statistics and epidemiology to public policy. What do you think of how the courts have handled the scientific evidence in radiogenic cancer cases?

Dr. MOSTELLER. I speak now from a personal opinion.

The CHAIRMAN. Surely.

Dr. MOSTELLER. I have not really seen a detailed study of this, but the instances that have been brought to my attention—some by Dr. Saenger and some by other members of our committee—have suggested to me that the treatment has been uneven. And indeed, the description that was given earlier by you, and I think others here, suggests that there is a lack of uniformity in what happens in the tort cases.

The CHAIRMAN. It certainly indicates that there is no uniform justice across the board; wouldn't you agree?

Dr. MOSTELLER. I do agree.

The CHAIRMAN. Do you think that the science is too uncertain for the courts ever to rule in favor of the plaintiffs in radiogenic cancer cases?

Dr. MOSTELLER. I heard you ask that question earlier, and I do not actually understand it, Senator.

The CHAIRMAN. Well, I think what I am saying is that under the present tort law, you have to prove, generally by a preponderance of the evidence, that a certain ailment was caused by a certain cause. And what I am asking you is do you think that is an effective system to resolve these problems, or can you really recover under the present tort law—can plaintiffs recover?

Dr. MOSTELLER. It seems to me that you can often recover under the present tort law, because some people do. But whether it is a good systematic way of handling these very difficult problems is another question altogether.

The CHAIRMAN. In other words, it is an iffy situation at best.

Dr. MOSTELLER. Yes, sir.

The CHAIRMAN. And you really run into the problem of medical causation, of finding doctors who can say that this particular cancer was caused by this particular exposure to radiation; isn't that correct?

Dr. MOSTELLER. That is my understanding.

The CHAIRMAN. OK. Now, do you think that the preparation and review of the NIH report was adequate, on your committee's part, and how would you see the next edition of this report prepared?

Dr. MOSTELLER. I would like to see a standing committee established so that it can gather the additional data gradually, and so that there is not a crisis calculation, so that they can smooth in the results, for instance, from the Japanese dosmetry, and so that they can gather new information as fast as it comes in and work it into the tables. I think it has to be a slow job rather than a quick one.

The CHAIRMAN. How do you think the NIH report should be used—particularly, how do you feel the report should be used in the courtroom? Do you feel it might help to bring coherency to court proceedings on radiogenic cancers?

Dr. MOSTELLER. I believe it could. Whether the current system would allow it to or not, I do not know.

The CHAIRMAN. Dr. Saenger, I understand that the tables might not be applicable to cancer patients who have received radiation therapy. But many relatively healthy people get diagnostic x rays and dental x rays. Wouldn't the tables be applicable here, especially in light of the fact that some of these diagnostic and dental exposures in the 1950's were quite substantial?

Dr. SAENGER. The exposures that populations received in the 1950's, say, dental x rays and so on, to my knowledge, except for calculations, have never been demonstrated to show an increase, say, in cancer of the head and neck. It is extremely difficult with the low doses which are received by the so-called healthy individuals as might be represented by most of us in this room to attribute medical radiation as a cause of these cancers. I think we use these risk estimates in a preventive sense. This is what I tell my people, for radiation hygiene, to keep doses low enough for protection yet high enough so that when we use the radiation, we can find out what it is we want.

Now, to carry this one step further, if you look at the history of medical radiation, we now find that almost all uses of medical radiation for surveys of healthy persons have been eliminated, with the exception of the present study going on of mammography to detect carcinoma of the breast early in women. Other than that, all surveys have been discontinued, and you can find this in the report of the committee that I chaired for the International Commission on Radiological Protection, called "Protection of the Patient in Diagnostic Radiology."

I hope that answers your question.

The CHAIRMAN. It does.

Dr. Saenger, are there any qualitative differences between radiation exposures from natural resources and, say, medical procedures?

Dr. SAENGER. Are there qualitative differences? No, sir.

The CHAIRMAN. OK.

I want to thank you gentlemen for being with us.

Senator Grassley, we will turn to you at this time.

Senator GRASSLEY. Thank you.

It just so happens not only of this panel, but the others, the questions that I had to ask have already been covered.

But I did want to get the floor just to ask permission to insert a statement in the record.

The **Chairman**. Without objection, we will put it in the record at the appropriate place. Thank you, Senator.

Senator **Grassley**. Thank you.

The **Chairman**. I want to thank each of you. I think this has been a monumental start, and certainly, a monumental set of work being done, and even those who are critical on either side have to admit that it is a step in the right direction.

So I just want to thank you for the great work that you have done and hope that maybe we can follow your advice to have a standing committee that will more gradually assimilate these materials and correct any defects that may exist in the report which we do not know exist today.

Thank you so much for being here, and thank you for your testimony.

I am going to try and move through the last two panels. I may not be able to get to the last panel before I have to go to a policy committee meeting. What I would propose to do, if I cannot get through the last two panels, is that I would recess until 2, when I can get back and finish the last panel.

Our next witnesses will be Dr. Alvin Young and Dr. Randall Caswell, who are representatives of the Committee on Interagency Radiation Research Policy Coordination, which consists of people from every Federal agency that has a concern with radiation issues. This interagency task force has also followed the development of the radioepidemiological tables and has issued several white papers on the work of the NIH committee.

So, we are pleased to welcome you, Dr. Young. Is Dr. Caswell here?

Dr. **Young**. No, sir, he is not. He was not able to be here today. He is in Europe, attending a radiation meeting.

The **Chairman**. I understand. So we will ask him to get his testimony in, in written form, then.

Dr. **Young**. I will be presenting the only testimony today.

The **Chairman**. You will be the only one presenting. All right, we will proceed with you, Dr. Young, and we will go from there. If you can summarize, I would appreciate it. I would like to get that last panel done, so that they will feel good about being up this morning, and if I cannot, I will just have to do what I have to do.

STATEMENT OF DR. ALVIN L. YOUNG, SENIOR POLICY ANALYST FOR LIFE SCIENCES, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, AND CHAIRMAN, COMMITTEE ON INTERAGENCY RADIATION RESEARCH AND POLICY COORDINATION

Dr. **Young**. I will try to hit the highlights for you.

Late in 1983, Dr. Keyworth, the President's science adviser and Director of the Office of Science and Technology Policy, received a letter from Dr. Brandt, the then Assistant Secretary for Health, Department of Health and Human Services, asking him to coordinate the review of the report of the NIH ad hoc working group on the tables.

Dr. Keyworth accepted Dr. Brandt's request and subsequently assigned that responsibility to the Committee on Interagency Radiation Research and Policy Coordination [CIRRPC], a committee that I chair. Our committee is organized under the Federal Coordinating Council for Science, Engineering, and Technology within OSTP, and it is chaired by Dr. Keyworth.

Our committee, CIRRPC consists of 18 Federal agencies dealing in radiation matters.

I met with Dr. Brandt immediately after our assignment, and discussed with him the task that we would, in fact, perform a review.

The CIRRPC science panel, consisting of senior scientists from a complete cross-section of the Federal agencies involved in radiation research, reviewed the July 1984 and September 1984 drafts and the final report which was released in January 1985. The CIRRPC science panel produced a review of these documents, and I would like to submit, with your permission, the documents for the record.

Dr. Keyworth, in transmitting the CIRRPC's comments on the NIH report to Secretary Heckler, encouraged the Secretary to seek the broadest possible scientific review of the final report by placing in the Federal Register a notice of its availability for public comment.

My comments today will focus on the scientific considerations of the report, and particularly the views of the CIRRPC science panel.

First, the NIH report was prepared by an eminent group of scientists particularly well-qualified in radioepidemiology and related disciplines. It had the benefit of an independent arm's-length review of early drafts by both the National Academy of Sciences oversight committee for science content and by the CIRRPC science panel. As such, it should be viewed as an effort that reflects the best current knowledge on the relationship between cancer and radiation exposure.

Second, the radioepidemiologic tables intend to assist in estimating the likelihood that a cancer now present in a patient was caused by previous radiation exposure. This likelihood is not a certainty, and there is always a range of uncertainty about the tables' precise numerical values. The CIRRPC science panel was initially concerned that the uncertainties and, in some cases, limited scientific evidence, were not being adequately emphasized in the report. The panel stressed that users of the report had to appreciate the limitations that uncertainties placed on the determination of the tables' values for any individual cancer patient. Specifically, they suggested that statements in the NIH report, such as, "The tables can be regarded as no more than a guide to causation in the particular case" and the statement that "The tables cannot provide precise measures of the probability that certain cancers result from previous exposures" are important and should be emphasized from the outset.

The BEIR-III committee recognized the general uncertainties, especially at low doses, when it stated that,

> The Committee does not know whether dose rates of gamma or x-rays of about 100 millirads per year are detrimental to man. Any somatic effects at these dose rates would be masked by environmental or other factors that produce the same types of health effects as does ionizing radiation.

A third issue. The science panel and the NIH ad hoc working group agreed that with few exceptions, the tables deal with what is called low-LET radiation. We have heard a lot more about this, this morning. This form of ionizing radiation, which includes x rays and gamma rays, has significantly different risk factors from those of high-LET radiation, such as alpha particles and neutrons. Both groups emphasized that the tables should be used only in situations that match the conditions from which data were used to derive the tables' values.

Fourth, the tables were derived with few exceptions from information concerning external exposures of relatively short duration. There is little guidance as to how to apply the tables to internally deposited radionuclides delivering continuous doses to organs of the body. Although an extensive data base has been built up during the last few decades covering the effects of internal emitters in animals, the working group decided not to evaluate this source of information with respect to its applicability for the estimation of human risk. The science panel of the Radiation Committee feels that this omission, though understandable in light of the heavy pressures of time exerted on the working group, should not be continued indefinitely, but that a beginning should be made in examining and interpreting these data bases.

Fifth, the CIRRPC science panel has become concerned that the tables may be misinterpreted. The tables provide a retrospective evaluation, but cannot provide a prospective projection of radiation effects. An assigned value of 5 percent, for example, has in some instances already been taken by some to mean that an exposed person has a 5 percent chance of developing a specific cancer as a result of that radiation exposure—an erroneous interpretation. Rather, the assigned values are intended to apply to persons now having specific cancers, that is to say that there is a 5 percent chance that the cancer was caused by that radiation exposure.

The NIH working group did not address where, when, or how the tables may be applied. This is, however, the concern of your committee, as well as many elements of the Federal Government and ultimately, the public. I would caution that the use of the tables in their present form as a definitive scientific judgment concerning the probability of causation of radiogenic cancer for all types of radiation and exposure situations would be unwarranted. Limitations that the scientific community have been obliged to point out must not be lost in considering administrative solutions.

It took 2 years instead of one, as you know only too well, for some of our best statisticians, radiobiologists, and radiation epidemiologists to prepare the report. It was an immensely difficult and complex task to undertake. It is a good beginning; however, the job is not done. There are some gaps.

In summary, the CIRRPC review of the final report was done thoughtfully and with deliberation by the Federal scientific community to gain understanding of the concept of the tables. It is a valuable contribution to the accumulation of knowledge of radiogenic cancer in man. I believe it is now imperative for the scientific community at large, as well as interested elements of the public, to have the opportunity to review and comment on this report. There are limitations to the practical utility of the tables because of uncertainties and insufficiencies of scientific evidence in the low dose domain cited by BEIR-III, also in their applicability to high-LET radiation, radiation from internally deposited radionuclides, and in the determination of the absorbed dose at the cancer site in the body.

Again, I would emphasize that the tables were developed for the situation of a cancer having occurred, that is, the retrospective case. The tables are not applicable to the prospective case of estimating an exposed individual's risk of developing cancer at a future time.

Senator Hatch, this concludes my prepared statement, and I would be pleased to respond to questions.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Young and responses to questions submitted by Senator Simpson follow:]

STATEMENT OF

ALVIN L. YOUNG

SENIOR POLICY ANALYST FOR LIFE SCIENCES

OFFICE OF SCIENCE AND TECHNOLOGY POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

CHAIRMAN OF THE COMMITTEE ON
INTERAGENCY RADIATION RESEARCH AND POLICY COORDINATION

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

AND

SUBCOMMITTEE ON NUCLEAR REGULATION OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS, UNITED STATES SENATE

HEARINGS ON REPORT OF THE NATIONAL INSTITUTES OF HEALTH

AD HOC WORKING GROUP TO DEVELOP RADIOEPIDEMIOLOGICAL TABLES

June 11, 1985

Chairmen Hatch and Simpson and Members of the Committees:

I am honored to be here today as Chairman of the Committee on Interagency Radiation Research and Policy Coordination (CIRPPC) to comment on the National Institutes of Health (NIH) Report to Develop Radioepidemiological Tables, in this joint Senate hearing before the Committee on Labor and Human Resources and the Subcommittee on Nuclear Regulation of the Committee on Environment and Public Works.

Late in 1983, Dr. George Keyworth, the President's Science Advisor and Director of the Office of Science and Technology Policy (OSTP), received a letter from Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Department of Health and Human Services, asking him to coordinate the review of the Report of the NIH Ad Hoc Working Group to Develop the Radioepidemiological Tables among the federal agencies. Dr. Keyworth accepted Dr. Brandt's request and subsequently assigned CIRRPC the task of coordinating the views of all concerned federal agencies once the Report was available. CIRRPC was formed in April 1984 under the Federal Coordinating Council for Science, Engineering and Technology which Dr. Keyworth chairs. It consists of eighteen federal agencies dealing in radiation matters. I met with Dr. Brandt, and it was decided that CIRRPC would review and comment on drafts and interact with the Ad Hoc Working Group in briefing and information exchanges. This review, which was initiated in July 1984, was parallel to and totally independent of the work of the National Academy of Sciences' National Research Council Oversight Committee.

The CIRRPC Science Panel, consisting of senior scientists from a complete cross-section of the federal agencies involved in radiation research, reviewed the July 1984 and September 1984 drafts, as well as the

Ad Hoc Committee's Final Report of January 1985, and was briefed by members of the Ad Hoc Working Group.

The CIRRPC Science Panel produced a review of the September 1984 draft NIH Ad Hoc Committee Report which was transmitted to Secretary Heckler by Dr. Keyworth early this year. With your permission, I would like to provide Dr. Keyworth's letter and the CIRRPC Science Panel Report for the record. Dr. Keyworth, in transmitting the CIRRPC's comments on the NIH Report to Secretary Heckler, encouraged the Secretary to seek the broadest possible scientific review of the final report by placing in the Federal Register a notice of its availability for public comment. A critique of the Final Ad Hoc Working Group Report of January 4, 1985, has been completed by the CIRRPC Science Panel; and with the Committees' permission, it is also submitted for the record.

My comments today will focus on the scientific considerations of the Report, in particular the views of the CIRRPC Science Panel.

First, the NIH Report was prepared by an eminent group of scientists particularly well qualified in radioepidemiology and related disciplines. It had the benefit of independent, arm's length, reviews of early drafts by both the National Academy of Sciences' Oversight Committee for science content and by CIRRPC's Science Panel. As such, it should be viewed as an effort that reflects the best current knowledge on the relationship between cancer and radiation exposure.

Second, the Radioepidemiological Tables intend to assist in estimating the likelihood that a cancer now present in a patient was caused by previous radiation exposure. This likelihood is not a certainty and there is always a range of uncertainty about the Tables' precise numerical values. The CIRRPC Science Panel was initially concerned that the uncertainties and, in some cases, limited scientific evidence were not being adequately emphasized in the Report. The Panel stressed that users of the Report had to appreciate the limitations that uncertainties placed on the determination of the Tables' values for any individual cancer patient. Specifically they suggested that statements in the NIH Final Report, such as "...the Tables can be regarded as no more than a guide to causation in the particular case" (page 79) and "The Tables cannot provide precise measures of the probability that certain cancers result from previous exposures. . ." (page 116), are important and should be emphasized from the outset. The BEIR III Committee recognized the general uncertainties, especially at low doses when it stated that, "The Committee does not know whether dose rates of gamma or x-rays of about 100 mrads/yr are detrimental to man. Any somatic effects at these data rates would be masked by environmental or other factors that produce the same types of health effects as does ionizing radiation." (BEIR III Report, page 3). The Final Report, in its calculations assigned a numerical value to many of these uncertainties. CIRRPC believes that more research on this subject is needed, particularly with respect to the interaction between radiation and other carcinogenic agents.

Third, the Science Panel and the NIH Ad Hoc Working Group agreed that, with few exceptions, the Tables deal with what is called low linear-energy-transfer or low-LET radiation. This form of ionizing radiation, which includes x- and gamma-rays, has significantly different risk factors from those of high linear-energy-transfer or high-LET radiation, such as alpha particles and neutrons. Both groups emphasized that the Tables should be used only in situations that match the conditions from which data were used to derive the Tables' values.

Fourth, the Tables are derived, with few exceptions, from information concerning external exposures of relatively short duration. There is little guidance as to how to apply the Tables to internally deposited radionuclides delivering continuous doses to organs of the body. Although an extensive database has been built up during the last few decades covering the effects of internal emitters in animals, the Working Group decided not to evaluate this source of information with respect to its applicability for the estimation of human risk. CIRRPC feels that this omission, though understandable in light of the heavy pressures of time exerted on the Working Group, should not be continued indefinitely, but that a beginning should be made in the short term with the examination and interpretation of this database.

Fifth, the CIRRPC Science Panel has become concerned that the Tables may be misinterpreted. The Tables provide a retrospective evaluation but cannot provide not a prospective projection of radiation effects. An assigned value of five percent for example has in some instances already been taken by some to mean that an exposed person has a five percent chance of developing a specific cancer as a result of that radiation exposure -- an erroneous interpretation. Rather, the assigned values are intended to apply to persons now having specific cancers, i.e., there is a five percent chance that the cancer was caused by that radiation exposure.

The NIH Working Group Report did not address with where, when, or how the Tables may be applied. This is, however, the concern of your Committees, as well as many elements of the Federal Government, and ultimately, the public. I would caution that the use of the Tables in their present form as a definitive scientific judgment concerning the probability of causation of radiogenic cancer for all types of radiation and exposure situations would be unwarranted. The limitations that the scientific community have been obligated to point out must not be lost in considering administrative solutions.

It took two years, instead of one, for some of our best statisticians, radiobiologists, and radiation epidemiologists to prepare the Report. It was an immensely difficult and complex task to undertake. It is a good beginning; however, the job is not finished. There are some gaps for high-LET radiation, internally deposited radionuclides, the complex interactions of radiation and other carcinogens, and assessments on human characteristics and habits on the probability of causation. These uncertainties are not new; the BEIR III Committee, the 1979 Report of the Interagency Task Force on Ionizing Radiation, the 1981 Report of the Comptroller General to Congress, and the 1981 Report of the Interagency Radiation Research Committee have all cited, again and again, the formidable scientific barriers in estimating low dose effects in man. There have been continuous efforts to reduce uncertainties and enhance the confidence in the Tables' values. This research effort should continue by upgrading the Report and keeping up the momentum that your Committees have engendered.

In summary, the CIRRPC review of the final Report was done thoughtfully and with deliberation by the federal scientific community to gain understanding of the concept of the Tables. It is a valuable contribution to the accumulation of knowledge of radiogenic cancer in man. I believe it is now imperative for the scientific community at large, as well as interested elements of the public, to have the opportunity to review and comment on this report. There are limitations to the practical utility of the Tables because of uncertainties and insufficiencies of scientific evidence in the low dose domain cited by BEIR III, in their applicability to high-LET radiation, radiation from internally deposited radionuclides, and in determination of the absorbed dose at the cancer site in the body. Again, I would emphasize that the Tables were developed for the situations of a cancer having occurred, i.e., the retrospective case; the Tables are not applicable to the prospective case of estimating an exposed individual's risk of developing cancer at a future time.

This concludes my prepared statement. I would be pleased to respond to questions from Members of the Committee.

* * * * *

RESPONSE TO QUESTION BY SENATOR SIMPSON SUPPLIED FOR THE RECORD

Q: You mentioned the problems of determining the effects of high-LET radiation. Does this uncertainty lend credence to the claim that doses from the internal emitters make radiation exposures far more dangerous than the government claims?

A: It is recognized that so-called high-LET radiation, such as alpha particles, does result in very dense ionizations within biological tissue losing their energy in very short distances. On the other hand, low-LET radiation such as beta particles or gamma rays are relatively low in the number of ionizations they produce along their track in biological tissue. Thus, the energy deposited by ionizing radiation is much greater per unit of microscopic path length in tissue for high-LET radiation. For protection purposes a "quality factor" is usually assigned to normalize the potential hazard of radiation. Generally, a factor of 20 is assigned to alpha particles. When this is done, the resulting unit is the rem, a unit of "dose equivalent."

Radioactive materials can emit several different types of ionizing radiation, and thus when deposited in tissue as internal emitters can be so-called beta emitters (such as strontium-90), gamma emitters (such as cobalt-60), or alpha emitters (such as plutonium-239) or in many instances release multiple types (such as radium).

The CIRRPC's Science Panel recognized in its review that the NIH ad hoc Working Group on the Radioepidemiological Tables, with the exception of radium-224 and radon, did not specifically address "probability of causation" for clinically diagnosed cancers for internal emitters. However, in addressing external radiation exposure to low-LET radiation, some inferences can be drawn for those internally deposited radionuclides which are beta and gamma emitters because of similarities in ionization densities. However, such inferences are not appropriate to alpha particle emitters, generally.

A point to be recognized that when one takes into account the potential long-term retention of some internal emitters, they are not likely to be more dangerous per unit dose, but likely to be less dangerous due to conservatism in the modeling used in estimating dose and metabolic behavior for a given exposure condition. Additionally, because all radiogenic cancers are related to external exposure while only a few organs generally are involved in internally deposited radionuclides, the overall risk per unit dose is greater for whole body. This difference is accounted for in radiation protection by the use of weighing factors to equate the cancer risk to whole body risk.

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD
FOR DR. ALVIN YOUNG, WHITE OFFICE OF SCIENCE & TECHNOLOGY POLICY

Q1: Your review of the Ad Hoc Working Group's report identified a number of uncertainties in the "probability of causation" tables. Are you generally in accord with the testimony that has been presented by the Ad Hoc Working Group and the Oversight Committee on the nature and significance of those uncertainties?

A: Generally, yes. In our review of the final NIH Report we did identify some sources of concern but recognized that these concerns were not of such a magnitude as to result in any significant change in the table values.

Q2: Are the uncertainties of significant magnitude, in your judgment, that they warrant further scientific inquiry, prior to Congressional direction to use these tables and the accompanying report, as a guide for compensating cancer claimants exposed to radiation?

A: While continued scientific review will improve confidence in the methods used in analyzing existing data, and further research can reduce uncertainties, the report represents a credible analysis of current knowledge and provides values entirely consistent with our knowledge. Any major improvements would not be expected to occur in the short term, other than that which might be available within 3 to 4 years from the reassessment of the dosimetry for the Hiroshima-Nagasaki survivor populations and the ongoing examinations of the effects of high-LET radiations by the BEIR IV Committee of the National Research Council. While we continue to reduce many of the uncertainties, such as those in the dosimetry, variability of response to radiation by individuals will always exist.

The Administration does not believe that any Congressional direction is required in regard to the use of these tables and the accompanying report, particularly in view of the active program to make them useful tools in the compensation process.

Q3: I understand that the Veterans Administration has requested your assistance in reviewing the "probability of causation" methodology, for possible application in the regulations now being developed by the VA under the "Veterans' Dioxin and Radiation Exposure Compensation Standards Act." Please provide a status report on where this initiative stands, and what are the Administration's views on the use of these tables in that limited context.

A: Our review of the NIH Report in response to the request of the Administrator of Veterans Affairs is not complete. The Administrator of Veterans Affairs asked that CIRRPC provide recommendations on the dose level range and types of cancer for which the Radioepidemiological Tables might be applicable. We expect to provide such recommendations before the end of the year and to focus on the list of radiogenic cancers and values which can be used to screen out cancers and levels of exposure which in our opinion merit little, if any, further consideration. I would note that we are also examining from a policy viewpoint impacts of using the Report on Federal programs We expect this effort to culminate in a report published before the end of the year as well.

Q4: In your testimony, you allude to the potential impact of these tables on the process that we use for establishing radiation protection standards for occupational workers and other purposes. Would you explain the following statement: "The tables provide a retrospective evaluation but cannot provide a prospective projection of radiation effects"?

A: For the retrospective case, the clinical evidence for a given cancer is an existing fact, and therefore much relevant data is available, such as personal data, the individual's medical history, the family's medical histories, and occupational data that might include exposure to carcinogenic agents. This allows tangible evidence and other pertinent information to be considered when entering the Tables for a given radiation dose. It is retrospective in the sense that one is looking back from a clinically diagnosed cancer to a variety of factors that may contribute to the given clinical observation; the probability of cancer has the value of one. However, if the tables were to be used in a prospective manner for the individual exposed to a given radiation dose, one would have to make assumptions as to the type of cancer that would develop and the time course of the development for the individual, a highly speculative projection, to say the least. The NIH Ad Hoc Working Group clearly recognized bounds on cancer prediction by stating that "In a situation in which a large number of people have received a moderate-to-large amount of radiation, the numbers of cancers of specific sites produced by that amount of radiation can be estimated. We cannot, however, predict which individuals will develop cancer."

Q5: Have you, or anyone in the Administration, undertaken a review of the "probability of causation" approach reflected in the Ad Hoc Group's report, and compared the results that you would reach applying this methodology to the results that the various courts and workmen's compensation boards have been reaching in radiation compensation cases, or in the awards made by the Veterans Administration?

A: No, I am not aware that anyone in the federal agencies has made this comparison. We are examining, as noted before, potential impacts of applying the concept of the PC tables on various sectors of society, including our present legal system.

QUESTIONS FOR RADIOEPIDEMIOLOGICAL TABLES HEARING FOR PANEL THREE (ALVIN YOUNG AND RANDALL S. CASWELL)

Q1: How much thought have you given to the use to which these tables might be put in any compensation methodology, and may we have the benefit of your views on this matter?

A: The Tables should not be used as the criteria by which one decides for or against compensation. The confidence level that one can place in the Table values is not yet at that point where such unequivocal application is justified. Many uncertainties in our knowledge and understanding still exist. However, the Tables are valuable in that they provide a needed perspective and treatise on the likelihood that a radiation dose received at some earlier time may have been a causative factor in a clinically observed cancer. For those conditions analagous to conditions existing for the original data base, the PC Tables may provide, also, a means of screening trivial cases which appear to be unwarranted based on available scientific evidence. For example, when the dose received has been only a few rads, the PC values for some cancers may be so small that even allowing for large uncertainties will not bring the PC value up to a level that warrants consideration of radiation as a causative agent.

Q2: More specifically, would you agree with the statement one of our later witnesses will make, to the effect that judges and lawyers should decide whether evidence on risk quotients is relevant and material to the causation question, or to any other issue, in a particular case?

A: Testimony regarding PC methodology has been offered in past radiation cases and is sure to surface in future radiation cases. Judges and juries have had to, and will need to, determine its relevance, materiality and persuasiveness. In this regard, the PC tables are only a small part of other evidence that jurors and judges need to consider on the causation question.

Q3: Do you know if the Executive Branch is at work on any additional recommendations on this general subject of how these tables should be used?

A: CIRRPC's Policy Subpanel on the Radioepidemiological Tables is currently identifying the issues and determining potential impacts on various sectors of society should the Tables be applied in decisions involving compensation for alleged radiation injuries. Potential impacts on programs of energy production, medicine, industry, regulatory procedures, workmen's compensation, and the U.S. legal system are being considered.

The CHAIRMAN. We are going to keep the record open for additional information that may be given. I understand Dr. Saenger wanted to submit some additional information for the record, which we will accept without objection.

In 1980, the Interagency Task Force on Compensation for Radiation-Related Illnesses unanimously supported the use of the probability of causation method for assessing radiogenic cancer claims. That is correct, isn't it?

Dr. YOUNG. Yes; as far as I remember; yes.

The CHAIRMAN. OK. The agencies represented on this commission are pretty much the same as the agencies represented on your committee. So I, therefore, would like to know whether your committee supports the same view.

Dr. YOUNG. The policy implications of the tables, sir, are the big issue for us, the big concern; the impact that they will have upon the Federal Government's programs.

Accordingly, Dr. Keyworth has, in fact, appointed a special policy committee to take a look at the policy implications. That committee has now been formed, it is now meeting, and we hope to have a report for you toward the end of this year.

The CHAIRMAN. Do the relevant agencies still support a probability of causation method, or was this just a figment of the Carter administration?

Dr. YOUNG. I cannot be certain of that, sir; I do not know.

The CHAIRMAN. Does CIRRPC feel that the NIH committee fulfilled its legal mandate and used the best scientific expertise and data available?

Dr. YOUNG. Indeed, they did, sir.

The CHAIRMAN. You mentioned the problems of determining the effects of high-LET radiation. Does this uncertainty lend credence to the claim that doses from the internal emitters make radiation exposures far more dangerous than the Government claims?

Dr. YOUNG. Well, certainly, the whole issue of the emitters is of concern to us at this point, and we continue to gather data and try to evaluate it. I am not enough of a scientist in this particular area to be able to give you a definitive answer on that. However, I would be delighted to provide it for the record.

The CHAIRMAN. OK. I would point out that radiation such as neutrons, betas and alphas are much more potent than low-LET radiation such as x rays, but some of the former will not penetrate the skin——

Dr. YOUNG. That is correct.

The CHAIRMAN [continuing]. While the latter will, of course, go right through the body, as I understand it. So you get the high-LET effects primarily by breathing in materials or eating them, is that correct?

Dr. YOUNG. The impact of radon, sir, is in this line and is a big concern to us, trying to assess radon with regard to the data collected by the researchers here and reported in the tables. It is something that we are attempting to assess through a panel review right now.

The CHAIRMAN. OK. You suggest that there should be a further review of the tables' report. How should this be done, and what kind of a review are you thinking of?

Dr. YOUNG. Scientific method, of course, is that in fact, a report like this should have a chance to be viewed by as many members of the scientific community as possible.

The CHAIRMAN. Sure.

Dr. YOUNG. In our correspondence to Secretary Heckler, we recommended that the tables actually appear within the Federal Register, or a notice be made of their availability, so that the scientific community at large, and the public, could obtain copies of it and take the time necessary to do a critical review.

I will say that when the final tables came out in January, it had taken more than 2 months for the CIRRPC science panel to come together and to do an evaluation of the final report, when they had previously done an evaluation of the draft. So it is a difficult problem. It takes time to do good scientific evaluation.

The CHAIRMAN. What are your views on how the next edition of the tables' report should be produced?

Dr. YOUNG. Certainly, with the new data coming on dose reconstruction, the data coming out of Japan has to be incorporated. There are a number of epidemiologic studies that are underway in this country—one that you have just recently heard about, of course, released by the National Academy of Sciences. All of these data, I believe, have to be incorporated into the tables in the next edition, and I would hope to see that occur.

The CHAIRMAN. OK. Do you feel that the NIH report represents an improvement over BEIR for assessing radiogenic cancer claims?

Dr. YOUNG. Indeed, I do, sir. An excellent effort by the NIH ad hoc working group.

The CHAIRMAN. OK. Do you perceive that any Federal agencies will use the NIH report, and how about the Veterans' Administration, for instance—how would the report be used by a Federal agency?

Dr. YOUNG. Mr. Walters, the Administrator of the Veterans' Administration, has asked the CIRRPC to take a critical look at how the tables might be used in providing guidance for that agency in its handling of the compensation claims for radiation. We are in the process now of doing that very exhaustive evaluation, trying to decide which cancer data are the better data, which of the data are better for which cancers, for what dose rates, and so on. That report, we hope to provide to the Veterans' Administration very soon, sir. It is not complete at this time.

The CHAIRMAN. Well, thank you so much, Dr. Young. We appreciate you coming and we appreciate your testimony and your report here today.

Dr. YOUNG. Thank you.

The CHAIRMAN. Thank you for being here.

Our fourth panel consists of representatives of the scientific community. I must note that Mr. Alvarez is the only one of today's witnesses who is not a scientist, but he is an informed spokesman, I have been told. We asked him to speak because we had great trouble getting those scientists to come who claim that radiation is more dangerous than is officially recognized.

We offered to let the National Committee for Radiation Victims enlist scientists for the panel, but that was to no avail. We contacted Dr. Johnson directly, and to his credit, we appreciate him being here. Dr. Johnson has been among the prominent critics of the NIH tables, the committee and, I might add, myself, and it is good to see you in the flesh, Dr. Johnson.

I am pleased to welcome you Mr. Alvarez, and you, Dr. Johnson, to the committee, and look forward to taking your testimony at this time.

STATEMENT OF ROBERT ALVAREZ, ENVIRONMENTAL POLICY INSTITUTE, AND DR. CARL J. JOHNSON, RADIATION EFFECTS SPECIALIST, DENVER, CO

Mr. ALVAREZ. Thank you, Mr. Chairman.

Mr. Chairman, I am Robert Alvarez, director of the nuclear power and weapons project of the Environmental Policy Institute. The Environmental Policy Institute is a not-for-profit public interest research, education, and lobbying organization, dealing in public policy on energy, natural resources, public health, and agriculture.

I am pleased and grateful for the opportunity to present our views relative to the radioepidemiologic risk tables prepared by the ad hoc committee. Since I was notified late Friday afternoon that I may testify before these two committees, I am not able to offer as detailed comments as I would have liked. Thus, I respectfully request that I be given a reasonable opportunity to present further information for the record at a later time.

The recently proposed radioepidemiologic risk tables represent the most recent chapter in the ongoing controversy over the public health impacts of Federal and commercial nuclear activities. This is a controversy that has been raging for about 30 years. To a large extent, these tables are a result of extensive congressional interest in the latent effects of exposure to low-level ionizing radiation, which began in the 1970's. As you know, Mr. Chairman, you have presided over several of these hearings on this matter. Not only was there extensive congressional perusal of the Federal radiation protection program; in 1978, an interagency task force on ionizing radiation was convened to also review this matter.

One of the basic recommendations of that task force was that there is a conflict of interest relative to radiation health effects research. Although Congress enacted legislation in 1978, giving the Department of Health and Human Services authority to coordinate Federal health effects research, this basic conflict of interest remains.

The Department of Energy, whose interest in radiation stems from its mission to develop nuclear weapons and promote nuclear energy, has been found to fund approximately 60 percent of all Federal radiation health effects research. As you know, Senator, you have recognized this problem, and in previous legislation dealing with compensation for downwinders, proposed to transfer this radiation health effects research to the Department of Health and Human Services.

We also felt that your giving the responsibility to the Department of Health and Human Services to develop these risk tables, I think is a step in the right direction.

However, I would like to make some comments about the process of the selection of the members. At issue here is not the credibility of the individuals, but rather, the credibility of institutions of Government, which have been found by congressional investigations and the courts to have abused its stewardship role in protecting American citizens from Federal nuclear activity. If this were not so, we would not be here today. The fact that the nuclear weapons bureaucracy has a monopoly control over radiation health effects research that only affects the outcome of compensation for latent radiation industry, but also radiation standards for millions of people, is of central importance to these proceedings. This is the crux of the matter, from our point of view.

The language in the legislation mandating the creation of the ad hoc committee was general enough to give the Secretary of HHS sufficient latitude in selecting members whose research reflects a range of views. Thus, a committee was selected which represents various disciplines, but whose views are consistent with those of official risk estimates. Unfortunately, the Department of Health and Human Services failed to include members of the committee whose research is at variance with official estimates of radiation risk, with the exception of Rosalyn Yalow, who Dr. Jablon has characterized as an extremist with a pronuclear point of view.

The degree of uncertainty about latent radiation effects at low doses is rather substantial, and as Senator Simpson noted earlier, radiation is perhaps one of the most studied of all known environmental hazards.

The committee membership is made up of a majority of scientists who have spent a considerable amount of time analyzing data on one particular study, the lifespan study of the Japanese atomic bomb survivors. It is therefore not surprising that the fundamental basis for the tables come from these data.

But there is a curious paradox that surrounds the study. Instead of providing reassurance about radiation risks this study, as we know more about it, has really widened the level of uncertainty.

For more than 33 years, the U.S. Government has supported this important followup of the 1945 nuclear bombings of Hiroshima and Nagasaki. The survivor study consists of approximately 80,000 people who were exposed to estimated doses of zero to 400 rads and who were alive in October 1950 when the followup began. By the mid-1970's, the survivor study had reached what many in the radiation protection community thought was a major landmark—it had become the main scientific reference for low-level external penetrating risk estimates. Now, several basic assumptions about the survivor study have come under serious question. In 1981, the radiation protection community was jolted when researchers at the Department of Energy's Lawrence Livermore Laboratory reported that radiation exposures from neutrons at Hiroshima were significantly lower than previously believed. Dose reconstructions based on the 1957 Plumbob nuclear test series in Nevada also came under question. Radiation doses to the survivors may have been two to three times lower.

Reliance on cancer mortality risk estimates is also under criticism, in light of data from tumor registries in Hiroshima and Nagasaki, indicating an incidence of radiation-induced cancer that may be two times greater.

The shift away from an absolute to the more conservative risk model for radiation-induced cancer by some scientists, including Mr. Jablon, increases the risk by another factor of two. Additionally, a new wave of long-latency cancers is now being reported among the survivors, indicating that the worst may not yet be over.

In the June 1984 issue of the British Journal of Epidemiology, and a more recent issue of the International Journal of Epidemiology, Dr. Alice Stewart has raised perhaps the most fundamental question of all: Does this study have any value in deriving risk estimates for low-level radiation?

And if I may just make a comment. Dr. Rall, I believe, was out of order in saying that the reason Dr. Stewart was not chosen was that she was past retirement age and had not published. I believe if he follows the literature on radiation health effects research, he would see that Dr. Stewart does indeed publish in scientific journals such as the International Journal of Epidemiology. He did note that his statement, when I raised this with him, was made in haste, and I hope he does issue a retraction on that.

One of the fundamental questions that Dr. Stewart raises is can the long-term effects of high-dose radiation be different from those of protracted low-dose exposure. And if she is correct, the method of linear extrapolation from high-dose studies for low-level risk is invalid.

The other thing that Dr. Stewart also suggests is that the Japanese atomic bomb survivors, by virtue of the extraordinary carnage they experienced, may constitute a highly abnormal population upon which you cannot project risks on a normal population. According to Dr. Stewart, the analysis of the A-bomb survivor study failed to account for two important factors. The first was the elimination of those in a poor state of health or nutrition. This so-called healthy survivor effect, although recognized in studies of disasters, was discounted in 1950, because it was thought that the population had returned to normal. In Hiroshima, the healthy survivor effect may have been intensified by a severe typhoon, which killed hundreds of convalescents a few weeks after the bombing. In both cities, the absence of food, water, antibiotics, shelter, and sanitary conditions certainly added to the risk of dying during the early aftermath of the bombings. For years, the healthy survivor effect bothered epidemiologists who had privileged access to the survivor data. For example, in a confidential report to the British Medical Research Council, written in 1959 after a site visit to Hiroshima and Nagasaki, epidemiologists Court Brown, Richard Dahl, and A.G. Bakke noted: “It must be presumed that many of those killed in Hiroshima would have developed leukemia had they survived.” So that the surviving population is a selected one.

The second major factor cited by Stewart was the long-term residual damage from high doses which may have extended well beyond 1950, particularly tissue destruction damage. Many survivors who suffered radiation destruction of their bone marrow, a vital immune system organ, may have not fully recovered and had parts of their marrow replaced with scar tissue or sustained permanent but subtle damage to marrow stem cells. Survivors with less than normal amounts of active bone marrow are more prone to die from all causes, especially infections.

By showing that noncancer mortality follows abnormally—shaped dose response curves, Dr. Stewart has been able to test her hypothesis of the "healthy survivor" effect. She also points to the evidence of widespread bone marrow damage in the form of excess dose-related deaths from aplastic anemia, an acute form of radiation injury which depresses marrow production of white and red blood cells.

The analysts for the A-bomb survivor study have rejected all exceptional findings for blood diseases other than leukemia as misdiagnoses. However, when they reclassified several of these deaths as leukemias, the number of aplastic anemias was still higher than expected.

After correcting for these two competing forces, Dr. Stewart implies that 10 times more people died from the A-bomb radiation after 1950 and that more than two-thirds of these deaths were from diseases other than cancer.

Now, in 1970, Dr. Stewart and her statistician, Mr. George Kneale, inadvertently challenged the survivor study when they published childhood cancer risk estimates based on the in utero exposure of British children in their massive Oxford Survey of Childhood Cancers.

I may add that this is probably the largest epidemiologic study of human exposure to radiation in the world. It comprises a sample of 15 million children born in Britain since the 1940's and constitutes over 20,000 cases and controls. It is an ongoing study.

In 1970, Dr. Stewart published a statement basically that a single x ray, given during pregnancy, could initiate a cancer in childhood. This estimate was quickly challenged by Mr. Seymour Jablon and Dr. Hiru Kato of the Radiation Effects Research Foundation. After analyzing data on A-bomb survivors exposed in utero, Jablon and Kato concluded that the survivors showed no significant risks of childhood cancer. By 1979, however, the U.S. Food and Drug Administration rejected the A-bomb survivor study, and advised medical doctors against the routine use of fetal x rays. By their action, the Food and Drug Administration implicitly recognized that the Japanese atomic bomb survivors constituted a normal population, not suitable for their regulatory purposes.

Now, I may add that the Oxford Survey of Childhood Cancer is indeed a mainstream study. You do not see doctors giving routine fetal x rays to pregnant mothers, and it is because of that study. And to say that Dr. Stewart is not a mainstream scientist is a misnomer.

Although Energy Department researchers continue to dispute Dr. Stewart and Mr. Kneale's findings on in utero exposure, the Food and Drug Administration has created a major crack in the foundation of the radiation protection standards system. Now, even Dr. Kato is wavering on this point. In March 1983, at a symposium in Middletown, PA, he presented survivor data which suggests a cancer effect from in utero exposure. Unfortunately, the ad hoc committee makes no reference to these recent findings.

If indeed the survivor study cannot be used to establish low-level radiation standards, what are the alternatives?

The answer may be found amongst the 600,000 people who have worked in Federal nuclear facilities since the 1940's. Unlike the survivors of Japan, U. S. radiation workers received low-level exposures which were individually measured and reported. And, as has been noted by Dr. Saenger, these badge readings appear to be fairly accurate. The sample size of the Energy Department radiation work force, 600,000 people, is large enough to dispel criticism of small numbers.

Radiation health effects amongst Federal nuclear workers also appear to be quite different from those of A-bomb survivors. Employees at the Hanford Plutonium Works in the State of Washington for the most part did not receive bone marrow-destructive doses of radiation, and show higher cancer risks than those based on extrapolation.

There is also an absence of excess leukemias, a pronounced effect amongst A-bomb survivors. This may or may not indicate that leukemia is more closely related to high doses. What the two groups have in common, however, is a dose-related excess of long-latency multiple myeloma, or bone marrow cancer. Although it was not believed to be radiation-related in the mid-1970's, multiple myeloma has become the most prevalent long-latency cancer amongst the A-bomb survivors. This particular phenomenon of multiple myeloma, in terms of the significance of it in the A-bomb survivors, is conspicuous in its absence in the discussion of the risk tables.

Now, it can be argued that some of these data have not been published and therefore should not find their way in such an important document. But this has not prevented members of this committee from citing unpublished documents to dispute findings at variance with the A-bomb survivor study.

Another important fact concerning the Department of Energy cohort studies. Last week, I released a report based on several unpublished reports of Department of Energy researchers, indicating that greater than expected risks of dying from malignant cancers in certain nonmalignant respiratory diseases were being experienced in 11 populations of Department of Energy nuclear workers. And in in some of the internal reports of the Department of Energy, they also believe that these studies are showing some basic differences with the A-bomb survivor study.

The handling of the DOE occupational cohort studies by the panel suggests that they, I think, have been dismissed out-of-hand, and I think they deserve further examination. Unfortunately, there are no members on the committee who have any firsthand experience in assembling populations on these data or analyzing them. There are critics of these on the panel, but none. Dr. Stewart happens to be one of the principal analysts, and has been publishing frequently on this matter.

Now, in one of the critiques published in the tables to dismiss the Hanford findings is a paper by Dr. Hutchinson, Dr. Brian McMahon, Mr. Jablon, and Dr. Land. In a recently discovered report done for the Nuclear Regulatory Commission in 1979, the data used by Hutchinson et al. was examined for its quality. The NRC report done by Kinetic Research, Inc., found that these data were not only very different from the data assembled by Dr. Mancuso, but would have provided a serious problem in any analyses conducted. They noted that, "The data we have received has doses and time intervals which are not possible in the data collection scheme purported to have been followed in the Hanford study."

In a strongly worded conclusion, the NRC report states, "Unfortunately, examination of the data and investigation of the background material has led to the conclusion that the data provided is not a consistent, reliable, and authentic representation of the true facts concerning the mortality and exposure experience of Hanford workers. In particular, the data does not represent the report that the data maintained as its most reliable source," which was Dr. Mancuso.

I am not aware if Dr. Hutchinson et al. are aware of this report, but if this report is correct, it calls into question the conclusion of this critique, and also calls into question their dismissal of the DOE occupational cohort studies.

I guess in conclusion, I believe that we have a situation here that can be likened to the scientific debate in the 16th century in Italy. There was a gentleman named Galileo, who was fiddling with a new invention called the telescope, and based on some observations, he came to a finding which other people had made earlier but had since forgotten—that the Earth may be revolving around the Sun. Because he reported this, he was sequestered for the rest of his life, and he was basically denounced because he was not part of the mainstream.

I think it is the people who are not part of the mainstream who often make the most valuable contributions to our scientific understanding, and that the continued pattern by Federal bureaucrats to exclude those people whose views are at variance with official estimates of risk, I think not only continue to perpetuate this problem, but I think is feeding into public mistrust of Federal radiation research.

In conclusion, the Environmental Policy Institute respectfully recommends that any risk tables for radiation—induced cancer be subjected to a Federal rulemaking review process. This will allow for a broader public discussion which includes scientific views at variance with official risk estimates. Without question, these tables represent a significant Federal action affecting the rights of thousands of American citizens. They should therefore be given the same kind of perusal and criticism as to actions like proposed changes in radiation exposure standards.

This concludes my testimony. Thank you very much.

[The prepared statement of Mr. Alverez and responses to questions submitted by Senator Simpson follow:]

ENVIRONMENTAL POLICY INSTITUTE

STATEMENT OF ROBERT ALVAREZ

BEFORE

JOINT HEARINGS OF

THE SENATE ENVIRONMENT AND PUBLIC WORKS SUBCOMMITTEE
ON NUCLEAR REGULATION

AND

THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

REGARDING

RADIOEPIDEMIOLOGICAL RISK TABLES

JUNE 11, 1985

218 D Street, S.E., Washington, D.C. 20003 (202) 544-2600

Mr. Chairman and members of the Committees, I am Robert Alvarez, Director of the Nuclear Power and Weapons Project of the Environmental Policy Institute (EPI). EPI is a non-profit public interest research, education and lobbying organization which addresses public policies on energy, natural resources, public health, national security and agriculture. I am pleased and grateful for the opportunity to present our views relative to the radioepidemiological risk tables prepared by the Ad Hoc Committee.

BACKGROUND

The recently proposed radioepidemiological risk tables represent the most recent chapter in the ongoing controversy over the public health impacts of federal and commerical nuclear activities. It is a controversy which has been raging for over 30 years. To a large extent, these tables are a result of extensive Congressional interest in the long term effects of ionizing radiation exposure which began in 1976, when the first Congressional Seminar on low-level ionizing radiation organized by EPI was held. (1) Investigations and hearings of several Congressional committees held between 1977 and 1980, not only broadened the public record on the scientific debate, but moreover, revealed serious deficiencies in federal radiation protection and research programs. This series of Congressional inquiries have documented; (a) a long standing pattern of federal misrepresentation and distortion of radiation hazards of radiation; (b) the supression of research damaging to official views; (c) the punishing of independent researchers whose findings indicate greather than expected radiation health risks and; (d) most importantly the magnitude of the public health legacy of the past four decades of civilian and military nuclear programs. (2) (3) (4) (5) (6)

We now know that some 250,000 military personnel took part in atmospheric nuclear weapons explosions at the Nevada Test Site and in South Pacific islands. Approximately 600,000 radiation workers have been employed in the federal nuclear program since the 1940's. Serious accidents involving large releases of radioactivity from federal nuclear facilities have taken place. Global Fallout from atmospheric weapons detonations have also taken their toll. Although, it is impossible to precisely quantify the total human health damage from atmospheric weapons tests, a dose estimate of 540 million person-rems has been made by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 1982). This dose if applied to the current range of dose/effect coefficients is expected to give rise to excess cancer deaths world-wide numbering between 58,000 and 3.8 million. (7) A 1979 Nuclear Regulatory Commission staff analysis calculates as many as 170,000 people will suffer adverse genetic damage from weapons fallout by the end of the century. (8) The effects of nuclear weapons fallout on a more local scale have been found to be convincing enough for the federal district court in Salt Lake City to levy damages against the federal government to compensate several residents living near the Nevada Test Site during the open air testing program. (9)

Much of this information was already known by 1979, when the Interagancy Task Force on Ionizing Radiation was convened under the chairmanship of the Department of Health, Education and Welfare. In 1980, after exaustive review of the situation, the Task Force issued a series of recommendations. The most important recommendation to the Committees today deals with federal radiation health effects research. The Task Force noted that the Energy Department funds over 60 percent of all radiation health effects research. DOE's interest in radiation stems from its missions to develop nuclear weapons and promote nuclear power. Not even in the most remote sense, is DOE a public health agency. The Interagency Task Force recommended that DOE's radiation health effects research program be transferred to a federal public health agency. (10)

Although Congress enacted legislation in 1978 giving the Department of Health and Human Services (formerly HEW) authority to coordinate federal radiation health effects research the basic conflict-of-interest remains. By not effectively controlling the basic research infrastructure for radiation, the Interagency Committee on Radiation Research, Chaired by HHS is window dressing for the monopoly of the nuclear weapons bureacracy over research affecting radiation standards and compensation in this country. That is the crux of the problem. Hence, it is no suprise that the Ad Hoc Committee authorized by Congress to prepare radioepidemiological risk tables is comprised of individuals who have made career investments into research supported by the nuclear weapons program.

At issue here is not the integrity of these individuals, but rather the integrity of institutions of government which have been found by the Congress, courts and agency investigations to have violated their stewardship in protecting the health and environment of American citizens from nuclear activities. If this were not so, we would not be here today.

EXCLUSION OF INDEPENDENT SCIENTISTS FROM THE AD HOC COMMITTEE

The language in the legislation mandating the creation of the ad hoc Committee was general enough to give the Secretary of HHS sufficient latitude in selecting members whose research reflects a range of views. However, members were selected whose views generally support estimates of radiation risk held by the federal nuclear program. Unfortunately, the Department of HHS failed to include scientists who have made original discoveries about radiation and health which also contradict federal policy on radiation risks.

The rationale for their exclusion is based on opinions of federal bureacrats that these independent researchers are not part of the "mainstream" of radiation health effects research. Another reason also offered by Dr. Rall, Chairman of the Ad Hoc Committee, is that these independent researchers, have not published anything of note in recent years in the archival scientific literature. Rall's statement reflects his lack of knowledge about the recent literature on radiation health effects. Since his comment was directed in part at Dr. Alice M. Stewart, I believe there needs to be some clarification about who Dr. Stewart is and what contributions to public health and radiation protection she has made and continues to make.

Dr. Alice M. Stewart is a Senior Research Fellow at the University of Birmingham England. She is a world renowned radiation epidemiologist who was the first to find an association between pregnancy x-rays and childhood cancer. (11) Despite the barrage of criticisms of Dr. Stewart's Oxford Survey of Childhood Cancers, (OSCC) subsequent surveys have confirmed Dr. Stewart's findings. (12) (13) (14) (15) (16) (17) Moreover, the OSCC was cited in the 1980 Encylopedia Britannica as the largest study on the effects on low-level ionizing radiation in the world. (17)Moreover, the OSCC is the largest study of the effects of low-level ionizing radiation in the world. The OSCC comprises a sample of some 15 million children born in Britain since the 1940's. There are over 20,000 cases and controls in the study. Dr. Stewarts' childhood cancer study has been accepted by the U.S. Food and Drug Administration, and the World Health Organization as evidence of increased cancer risks from fetal x-rays.

Dr. Stewart is also the principal analysist of a study of 30,000 radiation workers at DOE's Hanford plutonium works in Washington state. (10) Her publications in the scientific literature on radiation epidemiology now number 328. In the past decade, Dr. Stewart has published 55 papers, of which 10 were published since 1983. (See Attachment A) Dr. Stewart's publication record indicates that her research is more in the "mainstream" of public health than those of her detractors in the Federal Nuclear Bureacracy.

Excluding researchers who are not part of the so-called "mainstream" is a time-honored tactic which has been used by scientific and religious establishments for centuries. Rall's rationale harkens back to the 16th century when the Catholic church used it to attack Galileo and others who challenged the official view that the sun revolved around the earth. For his views, Galileo was subjected to house arrest for the remainder of his life. In modern times, radiation health effects researchers whose studies repudiate official views are subjected to a more gentile form of "house arrest" -- their funding is stopped and they are usually forced into premature retirement. History shows, more often than not, that the researchers who are not part of the "mainstream" make the most valuable contributions to scientific knowledge.

The preemptive exclusion of independent scientists from the ad hoc committee deserves closer examination by the Congress, particularly since the Department of HHS brought an individual, (Dr. Rosalyn Yalow) onto the committee in the middle of its deliberations, who Mr. Jablon (an ADHOC committee member) described to this committee as a pronuclear "extremist." Moreover, the Department of HHS chose to include on the ad Hoc Committee only those scientists who testified against the plaintiffs in the Allen V. U.S. case. Ironically, the scientists who testified on behalf of the plaintiffs were found to be more credible by the deciding judge.

SCIENTIFIC BIASES OF THE AD HOC COMMITTEE

The Committee membership also reflects a certain bias which is centered around the belief that one major study - the Life Span Study of the Japanese atomic bomb survivors should be used as the basis for radiation risk estimates. This is not surprising since a majority of the Committee membership is made up of individuals who have spent a considerable amount of time analyzing the data of the A-Bomb survivor study.

The debate over radiation health effects has been subject to an interesting paradox. Instead of providing reassurance, human studies that span several years often increase uncertainties about radiation risks. A case in point is the Life Span Study of the Japanese Atomic bomb survivors. For more than 33 years, the U.S. government has supported this important follow-up of the 1945 nuclear bombings of Hiroshima and Nagasaki. Since 1975, the study has been funded jointly by the United States and Japan under the auspices of the Radiation Effects Research Foundation (RERF).

The survivor study consists of 79,736 people who were exposed to estimated doses of 0 to 400 rads (radiation absorbed dose) and who alive in October 1950 when the follow-up began. By the mid 1970's, the survivor study had reached what many in the radiation protection community thought was a major landmark. It had become the main scientific reference for low-level external penetrating radiation risk estimates. Now several basic assumptions about the survivor study have come under serious questioning.

In 1981, the radiation protection community was jolted when researchers at the Department of Energy's Lawrence Livermore Laboaratory reported that radiation exposures from neutrons may have been significantly lower than previously believed. Dose reconstructions based on the 1957 "Plumbob" nuclear test series at Nevada also came under question. Radiation doses to the survivors may have been two to three times lower. (18)

Reliance on cancer mortality risks estimates is also under criticism in light of data from tumor registries in Hiroshima and Nagasaki indicating an incidence of cancer two times greater. The shift away from an absolote to a more conservative relative risk model for radiation-induced cancer by some scientists increases the risk by another factor of two. Additionally, a new wave of long-latency cancers is now being reported among the survivors indicating the worst is not yet over.

HIGH DOSE STUDIES MAY NOT BE VALID FOR LOW-LEVEL RADIATION RISK ESTIMATES

In June 1982 and 1984 issues of the British Journal of Epidemiology, and the Spring 1985, International Journal of Epidemiology, radiation epidemiologists Dr Alice Stewart and George Kneale raise perhaps the most fundamental question of all: Does the Japanese A-bomb survivor study have any value in deriving risk estimates for low-level radiation?

On the basis of data published by the Radiation Effects Research Foundation in 1978, Stewart and Kneale suggest that RERF analysts have confused long-term effects of tissue destructive high doses with single cell low dose effects. If they are correct, the method of linear extrapolation from high-dose studies for low-level radiation risk estimates as used by the Ad hoc committee, is invalid.

According to Stewart and Kneale, the RERF failed to account for two important factors. The first was the elimination of those in a poor state of health or nutrition during the first five years after the bombings. This "healthy survivor" effect, although recognized in studies of disasters, was discounted in 1950 because it was thought that the populations had returned to normal.

In Hiroshima the "health survivor" effect may have been intensified by a severe typhoon which killed hundreds of convalascents a few weeks after the bombing. In both cities, the absences of food, water, antibiotics shelter and sanitary conditions certainly added greatly to the risk of dying during the early aftermath of the bombings.

For years the "healthy survivor" effect bothered epidemiologists who had privilidged access to survivor data. In a Confidential report to the British Medical Research Council written in 1959 after a site visit to Hiroshima and Nagasaki, W.M. Court-Brown, Richard Doll and A.G. Baikie noted:

> "It must be presumed that many of those killed in Hiroshima would have developed leukamia if they had survived so that the surviving population is a selected one."

The second major factor cited by Stewart and Kneale was the long-term residual damage to tissue from high doses which may have extended well beyond 1950. Many survivors who suffered radiation destruction of their bone marrow, a vital immune system organ, may not have fully recovered and had parts of their marrow replaced with scar tissue or sustained permanent but subtle damage to marrow stem cells. Thus, survivors with less than normal amounts of active bone marrow are more prone to die from all causes, especially infections.

By showing that non-cancer mortality follows abnormally shaped dose/response curves, Stewart and Kneale have been able to test their "healthy survivor" hypothesis. They also point to evidence of widespread bone marrow damage in the form of excess dose-related deaths from aplastic anemia - an accure form of marrow damge that depresses marrow production of red and white blood cells. The RERF rejected all exceptional findings for blood diseases other than leukemia as misdiagnoses. When they reclassified several of these deaths as leukemia, however, the number of aplastic anemias was still higher than expected.

After correcting for these two competing forces, Stewart and Kneale imply that ten times more people die from the A-bomb radiation after 1950 and that more than two-thirds of the deaths were from diseses other than cancer. The RERF claims that between 1950 and 1974 only 415 people died, all from cancer.

FETAL RISKS

In 1970, Stewart and Kneale inadvertently challenged the survivor study when they published childhood cancer risks estimates based on the in utero exposure of British Children in their massive Oxford Survey of Childhood Cancers. A single x-ray, they reported, given during pregnancy could initiate a cancer in childhood. (19)

Their findings were soon disputed by Mr. Jablon and Dr. H. Kato of the RERF. After analyzing data on A-bomb survivors exposed in utero, Jablon and Kato concluded that the survivors showed no significant cancer risks. (20) By 1979, however, the U.S., Food and Drug Administration rejected the RERF data and advised medical doctors against the routine use of fetal x-rays. By their action, the FDA implicitly recognized that the A-bomb survivors constituted an abnormal population not suitable for their regulatory purposes.

The Ad Hoc Committee report notes that there is substantial evidence to suggest a relationship between exposure to the human fetus to ionizing radiation and childhood cancer. But they conclude, "it is difficult to reconcile an order-of-magnitude difference between risk estimates derived from studies of the frequency of x-ray pelvimetry and estimates derived from studies of patients given therapeutic x-radiation during infancy or A-bomb survivors exposed in utero or early childhood." This statement is questionable since even Dr. Kato of the RERF is wavering on this issue. In March of 1984, at a symposium in Middletown, Pennsylvania, he represented A-bomb survivor data which suggest a cancer effect from in utero exposure. (21) The Ad Hoc Committee makes no reference to these data. It can be argued that since these data have not yet been published, they cannot be used by the ad hoc Committee. However, this has not prevented the Committee from citing unpublished papers to dispute Dr. Stewarts in utero studies.

For most scientists, the fact that both prospective and retrospective surveys are in agreement about the increased cancer risks from in utero exposure is sufficient evidence of a casual association. The Ad Hoc Committee implies that evidence of a similar study of twins, which could settle the problem of casuality is not yet forthcoming. This year, a study published in the New England Journal of Medicine by professional colleagues of Dr. Land, (and hoc committee member) showed that the risk of childhood cancer was more than two times as high for x-rayed as for non-x-rayed twins. (22) By pretending that this study does not exist, the ad hoc committee clearly reveals a bias that can adversely affect public health.

Although the ad hoc committee spends a considerable amount of time discussing discrepencies in the low-dose in utero studies, they are silent about discrepencies in the A-bomb survivor study. It is difficult to believe that the a-bomb survivor study which (a) ignored all offspring of mothers(who died within 5 years of being exposed to A-bomb radiation and blast (23) and (b) Included 55 deaths from unknown causes, (24) has more to tell us about the cancer effects of low-level radiation than several surveys of pregnancy rays and childhood cancers.

FEDERAL RADIATION WORKERS:
AN ALTERNATIVE BASIS FOR RISK ESTIMATES

If indeed the survivor study can't be used to establish risk estimates for low dose radiation exposures, what are the alternatives? The answer may be found among the 600,000 people who have worked in federal nuclear facilities since the 1940's. Unlike the survivors in Japan, U.S. radiation workers received low-level exposures which were individually measured and reported. The sample size of Energy Department radiation workers is also large enough to dispel criticisms of small numbers. Recent studies by DOE sponsored researchers show increased cancer and non-cancer risks in 11 populations of DOE radiation workers. A report, about these studies I authored recently details the following: (see attachment B)

FINDINGS OF INCREASED CANCER AND NON-CANCER RATES AMONG DOE NUCLEAR WORKERS

1. A 36 year follow-up of 30,000 workers at the DOE's Hanford Plutonium Works in eastern Washington has reported an association between excess deaths from cancer of the bone narrow, pancrease and lung. The risks of dying from radiation - induced cancer at Hanford appears to be 10 to 30 times greater than current protection standards assume

2. A study based on 8,737 white male workers at the DOE's Oak Ridge National Laboratory in Tennessee indicates that maintenance and engineering workers at the Laboratory have high risks of dying from leukemia. The leukemia risks were shown to be associated with duration of employment and exposure to radiation.

3. Studies of some 7,112 white male workers at the Rocky Flats nuclear weapons plant near Denver, Colorado show increased risks of contracting brain tumors and malignant skin cancer.

4. A study of active workers at the DOE's Lawrence Livermore Laboratory shows excess risks of contracting malignant skin cancer and cancer of the salivary glands.

5. A study of workers at the DOE's Savannah River Plant near Aiken, South Carolina indicates significant risks of lung cancer and leukemia.

6. Based on a study of 6,400 white male workers at the Oak Ridge, Tennessee Y-12 Weapons Plant, the risks of dying from brain tumors and leukemia were found to be increased.

7. A study of 19,000 women who worked at the Tennessee Eastman Facility operated at Oak Ridge between 1943 and 1947 has found increased death rates from non-malignant respitory disease, cancer of the blood forming organs, brain cancer, and cancer of the uterus, cervix and skin.

8. A study of white males who worked at the same Tennessee Eastman Facility has established an increased risk of dying from lung cancer following exposure to uranium dusts.

9. Workers at the DOE's Fernald, Ohio Uranium Processing Plant show significant risks of dying from gastro-intestinal cancers and were shown to experience excess death rates from fibrosis of the lung following exposure to uranium dusts.

10. A study of 1,302 white male welders who worked at various Oak Ridge, Tennessee facilities between 1943 and 1977 show excess death rates from emphysema.

11. A study of 2,529 white male workers who received a total cumulative dose over 5 rems show increased death rates from cancer of the rectum.

Radiation health effects among federal nuclear workers appear to be different than those of the A-bomb survivors. Employees at the Hanford Plutonium Works in the state of Washington, for the most part did not receive bone marrow destructive doses of radiation and show higher cancer risks by at least an order of magnitude than those based on extrapolations. There is also an absence of excess leukemias, at Hanford a pronounced effect among A-bomb survivors. This may indicate that leukemia may be more closely related to marrow destructive High doses than single cell effects.

What the two groups have in common, however, is a dose-related excess of the long-latency multiple myeloma or bone marrow cancer. Although it was not believed to be radiation related in the mid 1970's multiple myeloma has become the most prevalent long-latency cancer among the survivors. (24) The ad hoc Committee claims that multiple myeloma is not a "radiogenic" cancer.

USE OF FLAWED DATA BY AD HOC COMMITTEE MEMBERS TO REJECT WORKER STUDIES

The Ad hoc Committee cites two papers as evidence for rejecting the use of occupational radiation studies for risk estimates. One of these is authored by two members of the Ad Hoc Committee (Jablon and Land). A report filed with the Nuclear Regulatory Commission (NRC) in 1979, found that the Hanford data used by Jablon, Land and others was very different from the data assembled by Dr. Thomas Mancuso, (who originally reported positive findings at Hanford in 1977) Moreover, Land's copy of the Hanford Data was seriously flawed. The data examined by the NRC contractor, Kinetic Research Inc., was the same set of data obtained by Dr. Land from DOE's Oak Ridge, Tennesee data processing center. According to the NRC report, these data "would have provided a serious problem in the interpretation of any analyses conducted." The Kinetic Research group noted, "the data we have received has doses and time intervals which are not possible in the data collection scheme reported to have been followed in the Hanfords study." In a strongly worded conclusion, this NRC report states, "unfortunately examination of the data and investigation of the background material.. has led to the conclusion that the data is not a consistent, reliable and authentic representation of the true facts concerning the mortality and exposure experience of Hanford workers. In particular, the data does not represent the reported state of the data maintained at its most reliable source."

It's not clear if the NRC never made this report known to the people who used these data to publish critiques of the Mancuso, Stewart and Kneale Hanford survey. If the NRC did inform them, there has been no effort to correct this situation. This episode, emphasizes the problems associated with establishing radiation risk estimates without broad participation by independent scientists. It certainly shows that the Department of Energy which funded Land, Jablon and others to attack the Mancuso study provided them with data which was found by an NRC group to be so flawed that it could not be used for a valid analysis. Yet, we now find it being used in a report of crucial importance for thousands of American citizens. In the attached report dealing with the DOE worker studies, I have included relevant portions of the NRC report in my report on the DOE Worker Studies. (See Appendix B of the Report)

SUMMARY AND CONCLUSIONS

In principal EPI is not opposed to the concept of radioepidemiological risk tables. However, the current report by the Ad Hoc Committee reflects a serious bias in favor of the nuclear weapons and power industry. Many members ofthe Ad Hoc Comittee have based their careers on funding from the departments of Energy and Defense for research which is compatible with the views held by the federal nuclear program -- namely that the risks of cancer induction from low-level ionizing radiation are very small. At issue here is not the integrity of these individuals but rather the integrity of the federal agencies which fund these individuals and which have violated their stewarship in protecting American citizens from the hazards of nuclear activities. If this were not so, we would not be here today.

The Department of HHS and the National Academy of Sciences (which reviewed the Ad Hoc Committee report) have violated basic principals of scientific freedom and responsibility by preemptively excluding independent researchers from this process. Their rationale for such exlusionary practice, as stated by Dr. Rall, Chairman of the Ad Hoc Committee are: (a) these scientists are not part of the scientific "mainstream" and: (b) these scientists have not published in recent years in the archival scientific literature. This criteria did not prevent the Department from including onto the Committee in the middle of their deliberations a scientist who had not done any origional research into the health effects of ionizing radiation and has been described by Mr. Jablon, of the Ad Hoc Committee as a pronuclear "extremist."

This is crass politics on the part of the Department of HHS masquerading as scientific objectivity. The stated Rationale for excluding independent scientists from the Ad Hoc committee is not borne by the facts. Examination of the scientific literature, clearly shows that scientists who were excluded from the Ad Hoc Committee, have not only made original contributions to the field but have a publication record far more extenisve that many of the Ad Hoc Commitiee members.

As history clearly shows, it was the independent scientists who warned the public about the radiation hazards of fallout from atmospheric nuclear weapons test explosions. The "mainsteam" of scientists, (defined as those whose research was acceptable to the federal nuclear program,) either remained silent or willfully distorted or supressed information which tended the support the independent critics. We forget that the ratification of the atmospheric test ban treaty is clear repudiation of the scientific "mainstream". In a 1980 lecture, at the Fifth International Congress on Radiation Protection, Dr. Lauriston Taylor, Former Chairman of the National Council on Radiation Protection, and a leading member of the "mainstream" conceded, "the public has come to realize that it has on occasion been told untruths or part truths about some radiation matters, primarily by government agencies. It can probably be argued that at the time information was concealed or distorted, there were considered to be acceptable political or economic reasons to warrant it." Taylor added that even today, "I believe a good case can be made for some misinformation that may be supplied to the public."

Taylor's candid and disturbing comments characterizes the kind of dynamic which compromises truly objective assessments of radiation risks by federal agencies. The present radioepidemiological risk tables prepared by the Ad Hoc Committee are no exception.

The codification of these tables in their present form, without substantial independent input from scientists whose views are at variance with official risk estimates is a serious mistake having major ramifications for thousands of Americans. These tables should be sent back to HHS with a mandate to Reconstitute the Ad Committee with a balance of scientists that represent both sides of the radiation health effects debate. At a minimum, these tables should be subjected to a public rule making procedure in accordance with the Administrative Procedures Act.

This concludes my statement. Thank you.

FOOTNOTES

(1) Proceedings of a Congressional Seminar on Low-Level Ionizing Radiation. A report transmitted by the Subcommittee on Energy and the Environment of the Committee on Interior and Insular Affairs, 94th Congress, Second Session, May 4, 1976.

(2) U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Health and the Environment, Effect of Radiation on Human Health, 95th Cong., 2nd Session, Serial Nos. 95-179, 95-180, Vols I and II. January 24-26, Feb. 8-9 14, and 28, July 11, 12, 13, 14, 1978.

(3) U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, U.S. Senate Committee on Labor and Human Resources, Subcommittee on Health and Scientific Research, U.S. Senate Committee on the judiciary (Joint Hearings), Health Effects of Low level Radiation, 96th Cong., 1st Session serial No. 96-41, April 1979.

(4) U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, Low-Level Radiation Effects on Health, 96th Cong. 2nd session, Serial Nos. 96-130, Vols. I and II April 23, May 24, and August 1, 1979.

(5) U.S. Congress, House Committee on Science and Technology, Subcommittee on Oversight and Investigation, Human Total Body Irradiation Program at Oak Ridge, 97th Con. 1st session, Sept. 23, 1981.

(6) U.S. Congress, House Committee on Science and Technology, Subcommittee on Oversight and Investigations, The Department of Energy's health and Mortality Studies, 97th Cong. 2nd session, May 19, 1982.

(7) These estimates are based on a range of risk coefficients as reflected by the 1980 BEIR III report (low range) and the estimates derived by Morgan (Sep. 1979 Bulletin of Atomic Scientists) from the Hanford Survey of Mancuso, Stewart and Kneale (high range)

(8) Memorandum for: Robert B. Minogue, Dir. Office of Research, from: Robert Alexander, Occupational Standards Branch, Re: Human Biological Effects of World-Wide Fallout from Nuclear Weapons Testing, U.S. Nuclear Regulatory Commission, Feb. 26, 1979.

(9) Allen V. U.S.A., Civil C-79-0515-J, U.S. District Court for Utah, Central Divisions, May 10, 1984.

(10) Interagency Task Force on the Health Effects of Ionizing Radiation, Report of the Work Group on Science, U.S. Dept. of H.E.W., 1979. p. 28.

(11) Stewart A.M., Webb, J and Hewitt, D. "A Survey of Childhood Maligancies," Brit. Med. J., 1958, i, 1495-1508.

(12) MacMahon, B., Prenatal Exposure and Childhood Cancer," J Nat. Cancer Inst., 1962, 28, 1173-1191.

(13) Diamond, E.L., Schmerler, H. Lilienfeld, A.M., "The Relationship of Intre-Uterine Radiation to Subsequent Mortality and Development of Leukemia in Children," AM. J. Epid., 1973, 97, 283-313.

(14) Stewart, A.M. and Kneale G.W., "Changes in the Cancer Risk Associated with Obsteric Radiography." Lancet, 1968, 1, 104-107.

(15) Gibson, R.W., Bross, I.D.J., Graham, S., Lilienfeld, A.M., Schuman, L.M., Levin, M.L., and Dowd, J.E., "Leukemia in Children Exposed to Multiple Risk Factors", N. Engl. J. of Med. 1968, 279, 906-910.

(16) Ford, D.D. Patterson, J.S.C., and Treeting, W.L., "Fetal Exposure to Diagnostic X-rays and Leukemia andd other malignant Diseases in Childhood," J. Nat. Cancer Inst., 1959, 22, 1093-1104.

(17) Harvey, E.B., Boice, J.D., Honeyman, M. and Flannery, J.T., "Prenatal X-ray Exposure and Childhood Cancer in Twins," N. Eng. J. Med. 1985, 312, 541-577

(18) Marshall, E., "New A-Bomb Studies Alter Radiation Estimates," Science, Vol. 212, May 1981.

(19) Stewart, A.M. and Kneale, G.W., "Radiation Dose Effects in Relation to Obstetric X-rays and Childhood Cancers," Lancet, 1970, i, 4.

(20) Jablon, S. and Kato, H., "Childhood Cancer in Relation to Prenatal Exposure to Atomic Bomb Radiation," Lancet,1970, 2 1000-1003.

(21) Kato, H., 'Current Evidence of the Japanese A-Bomb Survivors, "a paper presented at the Three Mile Island Public Health Fund Meeting, March 29, 1983. (Transcript available from Environmental Policy Institute).

(22) Op Cit Ref. 17

(23) Op Cit Ref. 20

(24) Kato, H., "Mortality in Children Exposed to the A-Bomb in utero, 1945-69" J. Epid., 1970, 93, 435-442.

(25) Op Cit Ref. 21.

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD

FOR ROBERT ALVAREZ

1. Each of the three panelists that preceded you at the hearing on June 11 identified a number of key uncertainties in the "probability of causation" tables that have been prepared by the Ad Hoc Working Group. Aside from your views on the basic assumptions reflected in developing these tables, would you comment on the uncertainties that have been identified, and give us your view of the magnitude of these uncertainties?

2. Are those uncertainties of sufficient magnitude that, at this stage, we should consider further scientific analysis of this concept, before using these tables as a guide for compensating individual cancer claimants?

3. Have you undertaken an analysis of the "probability of causation" approach, and compared the results that you would reach if this approach were applied by the courts in any of the cases that you have been involved in, rather than the traditional tort approach presumably applied by the courts?

4. If one were to adopt all of the assumptions that you have advanced on the relationship between radiation exposure and cancer, and proceed from that basis to develop "probability of causation" tables, is this a methodology that, from a scientific standpoint, you would support as a basis for compensating individuals exposed to radiation who later develop cancer?

5. The Veterans Administration is currently considering whether it should employ the "probability of causation" methodology in the regulations that it is now developing under the "Veterans Dioxin and Radiation Exposure Compensation Standards Act". Do you support the use of this methodology by the Veterans Administration, in that context?

6. Do you, or the organizations that you represent, have any current plans to undertake a detailed scientific review of this effort--similar to what was done by the Mosteller Oversight Committee--to provide us with an independent assessment of the initiative? If so, would you be willing to share your results with us?

7. If one is to accept the premise that, based upon our current scientific knowledge, it is next to impossible to prove that a given cancer was or was not caused by an earlier dose of radiation, how do you respond to the claim that, under our current tort approach to these cases, a claimant will either be overcompensated or undercompensated, depending upon where the judge decides to impose the burden of proof?

In a letter of May 17, 1985, E. Cooper Brown, of the National Committee for Radiation Victims, raised a number of questions about the assumptions and data that went into developing the probability of causation tables, arguing that those assumptions underestimate the risk of radiation. Along that line, please provide answers to the following questions:

A. Based upon your most recent data, how many cancers occur in the United States annually, from all causes?

B. Of this total number, how many are related to radiation exposure?

C. Of those related to radiation exposure, how many are the result of natural background exposure? How many are related to weapons testing and fallout?

ANSWERS TO QUESTIONS ASKED BY SENATOR SIMPSON BY ROBERT ALVAREZ

1. To a large extent the answer to this question is contained in my written testimony. To summarize, a major uncertainty relative to the radioepidemiological risk tables stems from the exclusive use of extrapolations from high dose studies and the unscientific rejection of an abundance of scientific evidence based on human populations exposed at low-doses. The underlying assumptions relative to extrapolations from high dose studies are:(a)the long range effects of tissue destructive doses (50+ rads) delivered over short period of time are the same as those for exposure to chronic fractionated doses -- namely cancer and (b); the populations from which these extrapolations are based are normal and hence can be used to estimate risks for radiation workers and members of the general public.

Both of these assumptions have been accepted without empirical support. In three recent papers by Stewart and Kneale (1)(2) (3), published data on the Japanese Atomic Bomb Survivors indicates that post 1950 deaths from radiation include a significant number of deaths from non-cancers resulting from residual damage from bone marrow destruction. They also demonstrate that dose/response curves for non-cancer mortality are abnormally shaped in a manner which indicates that the survivor population is select one in favor of the hardiest inviduals who survived up until 1950 when the post-bombing study was initiated. Comment by the authors of the risk tables about these recent papers are conspicuous in their absence.

Epidemiological studies based on direct observations at low-doses indicate that extrapolations from high dose studies understimate cancer risks by 10 to 30 times. (4)(5)(6)(7). For example, studies of children exposed _in utero_ consistantly show an order of magnitude difference in risks based on extrapolations. Several very large studies of pregnancy x-rays have been conducted since the 1950's, which are accepted by the majority of phisicians and the U.S. Food and Drug Administration. However, the authors of the Risk Tables dismiss these studies out of hand and contend that the A-Bomb survivor study carries more weight. This assumption has more to do with the career investments made by several risk table Committee members into the A-bomb survivor study, than an objective review of the scientific literature. It is difficult to believe that the A-bomb survivor study which (a) ignored all offspring of mothers who died within five years of being exposed to A-bomb radiation and blast and (b) included 55 deaths from unknown causes has more to tell us about the cancer effects of low-level radiation than several surveys of pregnancy x-rays and childhood cancers (8)(9)(10)(11)(12)(13)(14).

Studies of occupationally exposed groups also provide more precise information about radiation cancer risks than extrapolations. Unlike the A-bomb survivors, U.S. and British nuclear workers were invidually measured for radiation exposure. They recieved pre-employment health screening and have been followed for more than 30 years. Since the June hearings, a study published in the _British Journal of Medicine_ which followed 39,000 British nuclear workers for 33 years (1946-79) reported that the risk of dying from radiation-induced cancer is 15 times greater than extrapolations from high-dose studies.*Underscoring this study is a U.S. study done under contract with the U.S. Department of Energy, which indicates that workers at Oak Ridge National Laboratory hired before 1949 , who were under 39 years at date of hire and who recieved external radiation exposure have a nine fold increased risk of dying from all cancers than non-exposed workers at the laboratory.**

---

* see attachment A

** see attachment B

2. Yes.

3. No.

4. In principal my answer is yes, But, the basic mathematical models developed by the Risk Committee members would require extensive overhauling.

5. At this time the Veterans Administration has chosen not to incorporate the Risk Tables into their proposed regulations. I agree with their decision.

6. No. But, perhaps a more appropriate review group is the Office of Technology Assessment.

7. I do not agree with the premise that it is next to impossible to prove that a given cancer was or not caused by an earlier dose of radiation because this question confuses the quest for absolute scientific exactitude with the need to rectify an obvious situation where the government was negligent in protecting the health and well being of its citizens from federal nuclear activities. From the point of view of scientific criteria for the courts to follow, the U.S. government does have a responsibility which has been sorely neglected to provide official risk estimates based on all evidence in the scientific literature. Moreover, these risk estimates should be derived in a way which is free from the obvious conflicting interests which have seriously corrupted federal radiation health effects research.

7. A Based on the 1980 BEIR III report, (pp. 204&207) the normal expectation for cancer incidence among 1 million people in the United States in 181,560.

8. B. The answer to this question to a large extent is hypothetical. Although, U.S. government agencies have presented various estimates of radiation-induced cancer from various nuclear activivites these estimates are of the "hand waving" variety because they contain wide margins of uncertainty. For instance, official estimates of radiation exposures to people living in the vicinity of the Department of Energy's Savannah River Plant are based on extrapolations from calculated release figures. A dose estimate based on the actual radiological monitoring conducted by the U.S. government spanning a 30 year period indicates that doses to people living in the vicinity of SRP are quite higher than these extrapolations.* The difference in cancer risks between these two estimates of dose at SRP is also quite large. Therefore, the data base used by federal nuclear agencies to postulate overall radiological impacts of nuclear activities is flawed and not derived from empirical evidence in most cases.

Since you have asked a question which requires an answer of equal ambiguity, I would say the following: Medical radiation constitutes the single largest source of human-made exposure to ionizing radiation in the U.S. The radiological impact of nuclear facilities on communities XMMXWMXKMXX have not been adequately been determined. However, some evidence exists to show that these impacts are considerable. Occupational cancer studies indicate that federal nuclear workers on an industry-wide basis are experiencing greater than expected risks of dying from cancer.

---

* see attachment C

Perhaps a more appropriate question to ask is: How adequate are current federal radiation protection policies?

8.C The answer as to how many cancers are caused by naturally occuring or "background radiation" is again hypothetical. There are studies which show no cancer effect and there are studies which do.

Regarding, fallout from the detonation of nuclear explosions., the U.N. Scientific Committee on the Effects of Atomic Radiation (UNCSEAR) in 1982 presented estimates, based on fallout measurements and calculations of radioactive constituents on radioactive fallout clouds,of radiation exposure to the global poulation. These estimates must be looked at with skepticism since they assume a uniform distribution of dose, which is not the case. For instance, the Red River Valley region of the United States recieved the highest levels strontium-90 from fallout in North America. Northern Europe, Scandinavia and western Russia in particular, recieved higher concentrations of fallout than elswehere in Europe.

Given these uncertainties, the 1982 UNSCEAR report estimates that by the year 2000 the collective global dose from fallout will be about 540 million person-rems. Based on various risk estimates by various committees and scientists, this dose is expected to give rise to excess cancer cases ranging from 244,080 to 7,560,000.*

The lower estimate is based on the 1980 BEIR III report (relative risk for cancer incidence of 452 x 10^6 cancer cases per rem.) The upper estimate is based on the Hanford Survey of Mancuso et al, as postulated by Morgan (Sep. 1979, Bulletin of Atomic Scientists - 14,000 x10^6 cancer cases per rem.)

FOOTNOTES

1. Stewart, A.M., "Delayed Effects of A-Bomb Radiation: A Review of Recent Mortality Rates and Risk Estimates for Five Year Survivors," Journal of Epidemiology and Community Health. June 1982, 36 , No. 2, pp. 80-86

2.Stewart, A.M. and Kneale, G,W., "Non-Cancer Effects of Exposure to A-Bomb Radiation," J. Epid. & Comm. Health, 1984, 38, No. 2, 108-112.

3. Stewart, A.M., "Detection of Late Effects of Ionizing Radiation: Why Deaths of A-Bomb Survivors are so Misleading.", International Journal of Epidumiology. 1985, 14, No. 1, 52-56.

4. Kneale, G.W., Mancuso, T.F. and Stewart, A.M., "Hanford Radiation Study III: A Cohort Study of Cancer Risks from Radiation to Workers at Hanford (1944-77 deaths) by Method of Regression Models in Life Tables," British Journal of Industrial Medicine. 1981, 38, 156-166.

5. Stewart, A.M. and Kneale, G.W., Radiation Dose Effects in Relation to Obstetric X-Rays and Childhood Cancers," Lancet, 1970, i, p. 4.

6. Abd Elghany, N.A.K., "An Epidemiological Study of Cancer Mortality Among Workers Exposed to Occupational Low-Levels of Ionizing Radiation, Dissertation, University of North Carolina, Chapel Hill, N.C. 1983.

7.Beral V. et al., "Mortality of Employees of the United Kingdon Atomic Energy Authority, 1946-79." British Medical Journal , 1985, 291, 440-447.

8.Stewart, A.M.,Webb, J. and Hewitt, D., " A Survey of Childhood Malignancies," British medical Journal, 1958, i, 1495-1508.

9. MacMahon, B."Prenatal Exposure and Childhood Cancer," Journal of the National Cancer Institute, 1962, 28, 1173-1191.

10. Diamond, E.L. Schmerler, H. and A.M. Lilienfeld, " The Relationship of Intre-Uterine Radiation to Subsequent Mortaloty and Development of Leukemia in Children," American Journal of Epidemiology, 1973, 97, 283-313.

11. Stewart , A.M. and Kneale, G.W., "Changes in the Cancer Risk Associated with Obstetric Radiography," Lancet, 1968, 1, 104-107.

12. Gibson, R.W., Bross, I.D.J. et al."Leumekia in Children Exposed to Multiple Risk Factors," New England Journal of Medicine , 1968, 279, 906-910.

13.Ford, D.D. et al. "Fetal Exposure to Diagnostic X-rays and Leukemia and other Malignant Diseases in Childhood," Journal of the National Cancer Institute , 1959, 22, 1093-1104.

14.Harvey, E.B. et al., "Prenatal X-Ray Exposure and Childhood Cancer In Twins," New England Journal of Medicine, 1985, 312, 541-577.

ATTACHMENT A

Table B.45

All Cancer Mortality, Odds Ratios for External Radiation Exposure Stratified by Age at Hire, Year of Hire and Latency

Age at Hire	Year of Hire	Latency (Years)	Radiation Effect OR	CI
< 39			1.06	(0.74, 1.53)
	< 1949	< 30	9.43	(1.06, 83.90)*
		>=30	1.94	(0.90, 4.19)
	>=1949	< 30	0.88	(0.43, 1.83)
		>=30	0.13	(0.01, 3.99)
>=39			1.43	(0.99, 2.06)
	< 1949	< 30	2.03	(1.09, 3.77)*
		>=30	1.08	(0.46, 2.51)
	>=1949	< 30	1.61	(0.78, 3.30)
		>=30	0.40	(0.02, 10.02)

---

* $P < 0.05$

SOURCE: Abd Elghany, N.A.K., An Epidemiological Study of Cancer Mortality Among Workers Exposed to Occupational Low Levels of Ionizing Radiation, Doctoral Dissertation, 1983, University of North Carolina, School of Public Health.

(EDITOR'S NOTE: Due to printing limitations, an additional attachment (B) submitted by Mr. Alvarez was retained in the files of the Committee.)

ATTACHMENT C

ROYAL SWEDISH ACADEMY OF SCIENCE

AMBIO

A JOURNAL OF THE HUMAN ENVIRONMENT

External Gamma Radiation Around the Savannah River Plant

BY BERND FRANKE AND ROBERT ALVAREZ

REPRINT

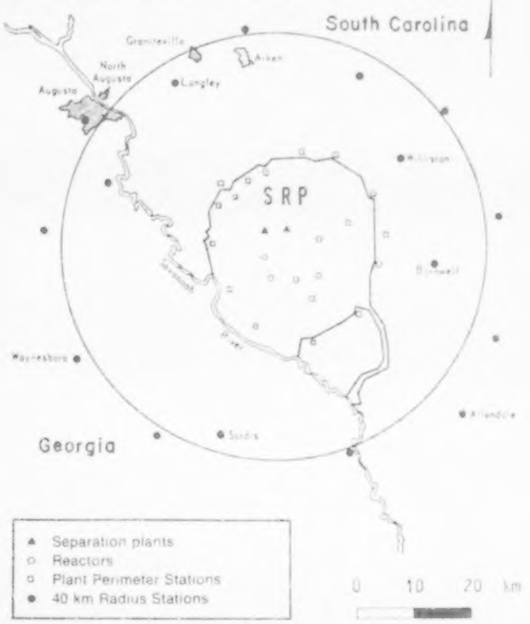
External Gamma Radiation Around the Savannah River Plant

Report

By Bernd Franke and Robert Alvarez

The Savannah River Plant (SRP) in South Carolina is presently the largest producer of nuclear explosives in the United States. It is owned by the U.S. Department of Energy (DOE) and has been in operation since 1952 under contract by E.I. du Pont de Nemours & Co. In 1953 the first of five reactors was started up. In the early years of the plant's operation, measurements of radioactivity did not cover all emission sources or all environmental media. For example, noble gas releases from the reactor area were not measured before 1971, and continuous monitoring of milk did not begin until 1962. A population dose assessment published in 1977 in an Energy Research and Development Administration (ERDA) report (1) was based on release estimates only. These obstacles would make a comprehensive environmental and health study a complex endeavor. Herein, environmental doses from external gamma radiation in the SRP vicinity are analyzed using the measurements taken by Du Pont. The results of this analysis are compared with data in the ERDA report and the inconsistencies are discussed.

Figure 1. Radiation background monitoring stations. Source: Reference 4, updated.



The Savannah River Plant has monitored the gamma radiation in its environment since 1952. For this study, all available environmental monitoring reports from 1952 to 1981 were analyzed (2). Starting in February, 1952, in the pre-operational period, radiation at the plant site was measured with S-22 ionization chambers. In November, 1958, Landsverk (L-65) pocket dosimeters were adopted and were in use until the end of 1965 (3). The relative response of the two devices to natural radiation was determined (4). The S-22/L-65 ratio was found to be 1.97 ± 0.74 (90 percent confidence level), implying that β and/or low-energy gamma radiations contributed approximately half the dose rate measured with the thinner-shelled S-22 chamber (3). In the present analysis, the data from the period February, 1952, to October, 1958, has been adjusted accordingly.

In 1966, the L-65 charge readers were replaced by thermoluminescent dosimeters (TLDs) with single LiF crystals. Around 1971, three detector units consisting of one CaF:Dy (TLD-200) extruded ribbon and two LiF:Mn (TLD-700) extruded ribbons were introduced (5).

The number of monitoring stations increased from 1952 to 1981. They have been grouped as indicated in Figure 1: the reactor area, the separation area, the plant perimeter, the 40-km radius and the 160-km radius (not shown). As the number of stations has changed, this grouping of the monitoring stations provides a more reliable interpretation. Measurement frequency changed from weekly (up to 1965) to monthly (1966–1972) to quarterly (after 1973).

RESULTS

Figure 2 shows the result of a comprehensive data collection, representing more than 10000 readings. All data were originally given in mR/d; they were converted to mrem/d using a conversion factor of 0.87 rad/R (air) (6), the coefficient of 1.1 (absorbed dose in muscle tissue/absorbed dose in air) (7) and the QF = 1 for gamma radiation. Data for the 160-km radius, where measurements began in 1972, are not included.

The radiation doses measured around SRP are a combination of external natural background radiation, fallout from nuclear weapons testing and SRP operations. The average doses during the period 1970–1981 at the plant perimeter, at the 40-km radius and at the 160-km radius were 66 mrem, 59 mrem and 79 mrem, respectively. These values are lower than the estimated average whole-body dose of 88 mrem received from external cosmic and terrestrial radiation, as given by ERDA (1) for the central Savannah River area. Because there were no major weapons tests during this period, and in order to keep the analysis consistent, these 1970–1981 averages were taken as "natural background" when calculating the increment due to nuclear weapons test fallout and SRP releases in the 1950s and 1960s. Also, the variations of background doses in the time period 1970–1981 were low: 0.182 ± 0.025 mrem/day for the plant perimeter, and 0.163 ± 0.014 for the 40-km radius. The pre-operational readings from February to September, 1952, 0.21 mrem/day for plant perimeter and 0.24 mrem/day for on-plant locations, were slightly higher by comparison.

The most distinct increases over background levels occurred from 1954 through the early 1960s; readings had gradually decreased to near-background levels by 1969. For the average of plant perimeter locations, the cumulative dose from July, 1954, to December, 1969, was 2206 mrem. In the same time period the cumulative average dose was 3896 mrem in the separation areas, 2993 mrem in the reactor areas and 1965 mrem for the 40-km radius. After accounting for the natural background radiation, offsite doses were approximately 130 percent higher than expected. The estimated increment was 1176 mrem at plant perimeter locations (July, 1954, to December, 1969) (8). Cumulative average plant perimeter values are slightly higher (+14 percent) than those for the 40-km radius. This ratio was higher in 1960 (+34 percent) and 1963 (+31 percent).

DISCUSSION

There are three possible explanations for these measured increases of gamma dose above the natural background radiation:

a) Fallout from atmospheric tests of nuclear weapons;
b) Releases from SRP facilities;
c) Erroneous measurements;

a) Compared to the external gamma dose increment measured at SRP, the fallout due to atmospheric nuclear weapons tests appears to be rather low. In Table 1, doses measured around SRP are compared with fallout doses measured and estimated from other locations in the U.S. and the United Kingdom. Around SRP, the measured dose increment above natural background radiation was 3.8 to 8.7 times higher than that which would be expected from fallout. According to the data in Table 1, only a small amount (presumably less than 30 percent) of the increment dose above natural background measured at SRP can be attributed to fallout from nuclear weapons tests.

b) ERDA estimates that for the period 1954 to 1975 the maximum total body dose commitment at the plant perimeter due to SRP atmospheric releases was 41 mrem. This is less than 2 mrem per year (1). Most of the dose is attributed, by ERDA, to tritium; at the plant perimeter the external gamma doses would thus be less than 1 mrem per year. Assuming this estimate to be correct, and fallout data from Table 1 to be applicable to the SRP area, the measurements around SRP in the years 1954–1969 were excessive by a minimum of a factor of two.

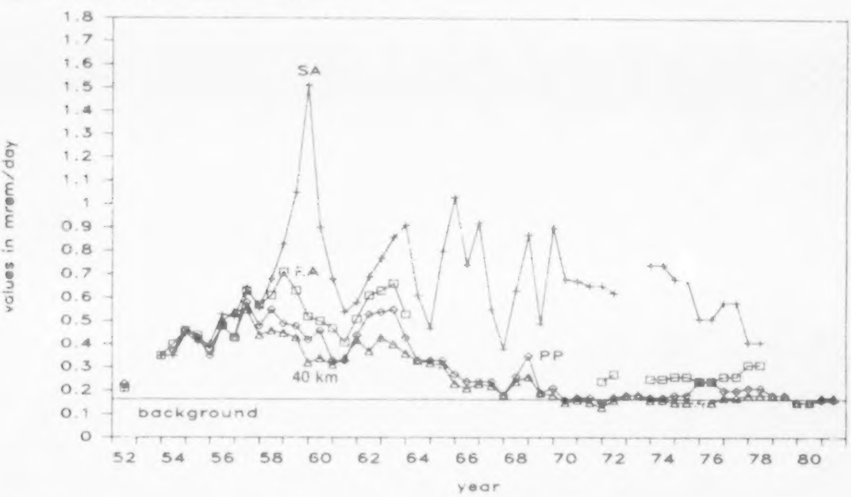
If, on the other hand, the releases of short-lived noble gases from the fission

Table 1. Comparison of external gamma doses around SRP with measurements of atmosperic weapons tests fallout.

Time Period		Fallout Dose	SRP[a]
July	1954–December 1969	68 mrem at Atlanta, GA[b]	590 mrem
January	1958–December 1966	62 mrem at New York, NY[c]	240 mrem
January	1961–December 1967	130 mrem at Grove, UK[d]	1,100 mrem[e]
July	1960–December 196[illegible]	76 mrem at New York, NY[f]	420 mrem

[a] incremental dose above natural background at plant perimeter
[b] external infinite gamma doses extrapolated from gummed film Sr-90 fallout data, after (30)
[c] 30-year gamma dose committment (infinite plane), calculated from fission product fallout, after (31)
[d] estimate of integrated dose, based on calculations and dose rate measurements, after (32)
[e] July 1954–December 1967
[f] total integrated open field dose, calculated from measured fission product fallout, after (33)

Figure 2. Summary of measurements of external gamma radiation at the Savannah River plant 1952–1981, with values in mrem/d. Averages of locations at: SA (+) = separation areas, RA (□) = reactor areas, PP (◇) = plant perimeter, and 40 km (△) = 40 km radius.



product content of reactor D_2O coolant were higher than estimated in (1), these higher environmental doses could be explained. Prior to 1961, SRP's reactors had no containment systems. A rough dose assessment, based on the inventory of short-lived Kr- and Xe- isotopes (9) and estimates of dose per unit of activity released (10) indicate that approximately 0.01 percent of the theoretical annual production of short-lived noble gases in the five SRP reactors could have caused the observed increase above natural background.

Without significant differences of incremental dose rates (the ratio 40-km radius/plant perimeter locations is only 0.86 on average), it is difficult to attribute this dose to SRP releases. Theoretically, the dose rates should decrease by a factor of two at the 40-km radius (11). Atmospheric conditions during the SRP releases should, therefore, be analyzed in regard to the inconsistency between gamma dose rates measured at the plant perimeter and those at the 40-km radius. It is also conceivable that the increase in gamma dose rate was due to deposited radionuclides from SRP's separation plants and reactor facilities rather than to noble gases released by SRP.

c) In a recent comment by Du Pont (12), it is stated that the pre-1966 measurements "were erratic due to ion-chamber leakage currents." According to (4), the chambers were leak-tested before they were used, pairs of chambers were exposed, and only the lower readings were reported. Nevertheless, leakage errors cannot be completely eliminated.

In all likelihood, if a leakage error by a factor of 2 had occurred between 1954 and 1964, this would indicate that the 1952 preoperational readings were also erroneous. However, the 1952 readings were only 0.03–0.05 mrem/day higher than the background measured by TLDs in 1970–1981. The maximum potential leakage error is, therefore, assumed to be 0.05 mrem/day. However, the difference may also have been due to fresh weapons-tests fallout in 1952. Furthermore, we would expect a sharp drop of measured dose rates in the year 1966, when TLDs were introduced. The difference in measured dose rates 1965/1966 was +0.25 mrem/day (separation areas), −0.08 mrem/day (plant perimeter) and −0.1 mrem/day (40-km radius), indicating an unclear correlation. It is unlikely that measurement errors are the main factor in an increase of gamma doses. Only an experimental calibration of the chamber used could clarify this question (13).

Even if we allow for a leakage error of 0.05 mrem/day and assume a dose contribution due to fallout of 30 percent, about 633 mrem of the measured increase in cumulative dose at the plant perimeter between 1954 and 1969 still remains unexplained. Emissions from SRP operations cannot be ruled out as a major source of this additional exposure.

Event on March 14, 1955

A large surface contamination was detected by the Health Physics Survey Group on March 14, 1955. Figure 3 is an isoactivity map showing that an entire area approximately 80 km long and 15 km wide had Thyac readings of more than 2000 counts per minute. Cumulative doses were about 12 mrem (14). The SRP report (19) concludes that since no unusual releases were detected in the separation area, and the observed half-life of 30 to 40 hours was too brief, "it appeared that the material was fallout from the Nevada atomic test and could be expected to extend over a large area." In recent comments by Du Pont (15) it was stated that radiation monitoring from the reactors indicated that an accident did not occur. This data, however, is not publicly available. As the center of the contamination was located around the reactors K, L and P, a release from these areas could be considered a likely source of the contamination, deposited by rainfall after at least 12 hours of atmospheric dispersion.

Du Pont attributes the observed activity pattern to fallout from the Teapot/Hornet test, deposited by a light rainfall (15). The test occurred at the Nevada Test Site at 8.20 EST on March 12, 1955, with a total yield of 4 kt at 90 m height (16). The decay of the unusual contamination near SRP would indeed be consistent with the decay of 2.25 day-old fission products from a nuclear weapons test (decay with $t^{-1.2}$, where t is time since detonation). A similar decay curve with a comparable fit, however,

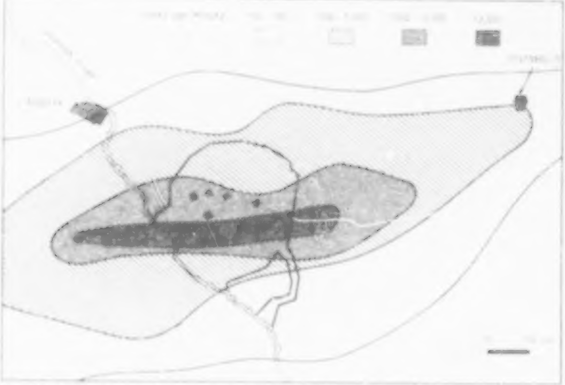


Figure 3. Isoactivity map of the SRP area on March 15, 1955. Source: Reference 19.

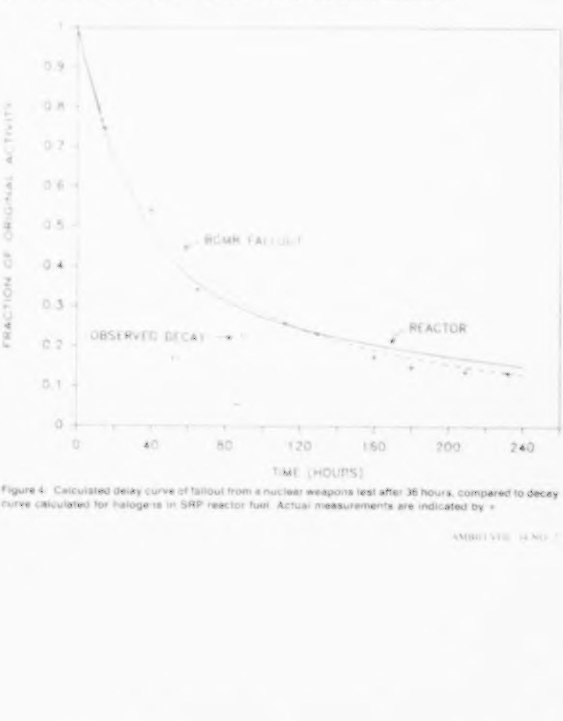


Figure 4. Calculated decay curve of fallout from a nuclear weapons test after 36 hours, compared to decay curve calculated for halogens in SRP reactor fuel. Actual measurements are indicated by +

would result if we attribute the activity to halogens (iodine and bromium isotopes) from SRP reactor fuel at about 100 hours after unloading from the reactor (see Figure 4) (17). But what did actually happen?

A trajectory at 18000 feet was estimated (18) for fallout from the Teapot/Hornet test to have passed over North Carolina. It is interesting to note, however, that the center of fallout on March 14, as actually measured with gummed film stations, was located over Wisconsin, Illinois, Indiana and Kentucky. The maximum reported value in (18) was 0.6 μCi/m² in Louisville, Kentucky. The two stations nearest SRP, Atlanta, GA, and Charleston, SC, reported 0.15 and 0.002 μCi/m². Assuming that the observed activity around SRP was from the Hornet test, we can assess its magnitude from fallout at SRP, where the dose rate was 0.3 mR/hr, measured on site with a gamma scintillometer one hour after the rainfall (19). According to the calculations by Hicks (20), the observed dose rate would be equivalent to a fallout of 45 μCi/m² two days after the test. This is about 100 times higher than the maximum fallout observed in Kentucky. If the dose rate of 0.3 mR/hr was representative for the plant site, the total deposition for 6100 km² around SRP (shaded area in Figure 1) would correspond to more than 1.5 percent of the total fission products from the Teapot/Hornet test. In comparison, as an average for all Upshot-Knothole tests in 1953, only 0.4 percent of the total fission products had been deposited over the continental United States by the second day after the shots (21). As a further comparison, the "hot spot" observed on April 26, 1953, deposited in upstate New York after torrential rains, was from a detonation 11 times larger than Teapot/Hornet and resulted in a gamma dose rate of 0.4 mR/hr (22). Thus, an extreme fallout situation must have occurred at SRP, more than 3200 km from the Nevada Test Site. In the absence of other evidence, an accidental release of radioactivity at SRP would be a more plausible explanation for the observed radioactivity in the plant vicinity.

Potential Consequences

The radiation doses unaccounted for around SRP may have induced a significant number of health effects in people who live and work in the SRP vicinity. This can be shown with a rough estimate. The doses measured at the 40-km radius are taken as representative for the population living within 80 km of the SRP center. This assumption is reasonable, as the majority of the population lives within the 30- to 50-km annulus. The cumulative average dose in this area for July, 1956–December, 1969, affecting all 465000 inhabitants, would be 600 mrem above natural background. This estimate takes into account a 33 percent reduction due to shielding effects (23). Thus the population dose would be approximately 280000 person-rem for the 80-km radius, compared to the ERDA estimate of 6651 person-rem for the 100-km radius (1954–1975) for atmospheric releases by SRP only (1).

For a population dose of 280000 person-rem in the 80-km radius around SRP, the estimated number of cancer cases would range between 60 (BEIR III risk factor) (24) and 2000 (risk factor from the Hanford Study by Mancuso, Stewart and Kneale) (25). Using the ERDA dose estimate, between 2 and 50 cancer cases would be attributable to SRP operations.

A recent mortality survey (26) based on official vital statistics (1949–1978 deaths) suggests that no significant adverse health effects have been detected in the vicinity of SRP. This survey was examined by a committee of the U.S. Department of Energy, which assigned it a "low" priority because

a) its statistical power was low;
b) it was insensitive to changes in disease trends, and
c) the study's findings may have been diluted by migration patterns (27).

Moreover, the survey does not allow for cancer latency periods identified in other more extensive surveys (28, 29).

Therefore, a more sensitive cohort survey of people who lived near SRP during the 1954–1969 period may be more helpful in determining whether adverse health effects are occurring as a result of excess radiation doses measured near the plant.

References and Notes

1. Energy Research and Development Administration: Waste Management Operations, Savannah River Plant, Aiken, South Carolina: Final Environmental Impact Statement, ERDA-1537, September 1977.
2. The series numbers of the reports, published by E I Du Pont de Nemours and Co, Savannah River Plant, Aiken, SC, are in chronological order: DP-27; DP-92; DPSP 55-25-54; DPSP 56-25-13 (DEL); DPSP 56-25-54 (DEL); DPSP 57-25-4 (DEL); DPSP 57-25-15 (DEL); DPSP 57-25-43 (DEL); DPSP 58-25-17 (DEL); DPSP 58-25-36 (DEL); DPSPU 59-11-23; DPSPU 59-11-30; DPSPU 60-11-9; DPSPU 60-25-25 (DEL); DPSP 61-25-4; DPSP 62-25-2; DPSP 62-25-9; DPSP 63-25-3; DPSP 63-25-5; DPSP 63-25-10 (DEL); DPSPU 64-11-12; DPSPU 64-30-2; DPST 71-30-1; DPST 65-302; DPST 66-302; DPST 67-302; DPST 68-302; DPST 69-302; DPST 70-302; DPST 71-302; DPSU 72-302; DPSPU 73-302; DPSPU 74-30-1; DPSPU 75-302; DPSPU 76-302; DPSPU 77-302; DPSPU 78-302; DPSPU 79-302; DPSPU 80-30-1; DPSPU 80-30-1; DPSPU 81-30-1; DPSPU 82-30-1.
3. Beginning with November 1958, doses were reported as gamma dose rate in air; before this time, values were given in mrep units.
4. J E Hoy, L F Landon: Background Radiation Measurements in the Environs of the Savannah River Plant, 1952–61. In: The Natural Radiation Environment (J A S Adams, W M Lowder, Eds) Rice University, Semicentennial Publications, University of Chicago Press (1964), pp 797–806.
   Taking the range of the S-22/L-65 ratio of 1.23–2.71 into account, the resulting dose range would be 2127 to 2383 mrem (July 1954–December 1969 at plant perimeter locations).
5. J E Hoy: Environmental Radiation Monitoring with Thermoluminescent Dosimeters. *Health Physics* **21**, 860–862 (1971).
6. F W Whicker, V Schultz: Radioecology: Nuclear Energy and the Environment. CRC Press, Boca Raton, Florida (1982).
7. BI-Taschenlexikon Radioaktivität (J Leonhardt, Ed.), VEB Bibliographisches Institut, Leipzig (1982).
8. Expected at the plant perimeter from July 1954 to December 1969: 15.5 × 365 × 0.182 = 1030 mrem; at 40-km radius July 1956–Dec 1969: 13.5 × 365 × 0.163 = 803 mrem.
9. A G Evans: Noble Gas and Halogen Source Terms for the SRP Reactor Safety Analysis Report. DPST-82-745 (1982).
10. DPSPU 80-30-1.
11. According to DPSPU 78-30-1, p 37, the average radiation dose commitment from SRP releases, to individuals 80 km from the center of the plant, is about 30 percent of that received by people at the plant perimeter. Extrapolation to 40-km distance derives the factor of two.
12. R W Benjamin *et al*: E I Du Pont de Nemours & Co, Aiken, SC, November 18, 1983.
    W L Marter, Savannah River Laboratory, Aiken, SC, December 31, 1984, DP-MS-24-145.
13. The uncertainty in the beta-gamma/gamma ratio of the S-22 ionization chambers used until 1958 cannot be the reason for the observed increment. Without the S-22 data, the cumulative dose at plant perimeter of 1825 mrem (Jan '57–Dec '69) was 112 percent higher than the 864 mrem expected from natural background.
14. Extrapolated from the gamma dose rate of 0.3 mR/hr (see Reference 19) one hour after the rainfall.
15. R W Benjamin *et al*, Reference 12.
16. M W Carter, A A Moghissi: "Three decades of nuclear testing." *Health Physics* **33**, 51–71 (1977).
17. Based on source term data from A G Evans, "Noble Gas and Halogen Source Terms for the SRP Reactor Analysis Report," Savannah River Laboratory, August 9, 1982, DPST-82-745.
18. R J List: Radioactive Fallout in North America from Operation Teapot, February 1956, NYO-4696 (DEL).
19. DPSP 56-25-13 (DEL).
20. H G Hicks: Results of Calculations of External Gamma Radiation Exposure Rates from Fallout and the Related Radionuclide Compositions. Operation Teapot, 1955. UCRL-53152 Pt 5 (1981).
21. R J List: The Transport of Atomic Debris from Operation Upshot-Knothole. NYO-4602 (DEL) (1954).
22. H M Clark: The Occurrence of an Unusually High-Level Radioactive Rainout in the Area of Troy, N.Y. *Science* **119**, 619–622 (1954).
23. H A Knapp: Gamma Ray Exposure Dose to Non-Urban Populations from Surface Deposition of Nuclear Test Fallout. USAEC-Report TID-16457, Division of Biology & Medicine, Washington, D.C. (1962).
24. Coefficient for Linear Dose Response Relationship: Committee on the Biological Effects of Ionizing Radiation (BEIR): The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980, Washington, D.C. National Academy of Sciences (1980).
25. K Z Morgan: Risk of Cancer from Low Level Exposure to Ionizing Radiation. *Bulletin of the Atomic Scientists*, September 1978, pp 30–40.
26. H I Sauer: Mortality Trends in Counties near the Savannah River Plant, 1949–1978. E I Du Pont de Nemours and Co, July 1984.
27. U.S. Department of Energy, Office of Health and Environmental Research, p 13: Epidemiological Projects Considered Possible to Undertake in Populations around the Savannah River Plant, provided by the Epidemiological Consultants, October 25–26, 1983.
28. T F Mancuso, A M Stewart, G W Kneale: Hanford Radiation Study III: A Cohort Study of the Cancer Risks from Radiation to Workers at Hanford (1944–77 deaths) by Method of Regression Models in Life Tables. *British Journal of Industrial Medicine* **38**, 155–166 (1981).
29. H Kato, W J Schull: Cancer Mortality among Atomic Bomb Survivors, 1950–78. Hiroshima, Japan: Radiation Effects Research Foundation, 1980, Life Span Study Report No. 9, RERF TR 12-80.
30. J H Harley: Summary of Gummed Film Results through December 1959. HASL-93 (1960).
31. W R Collins Jr, G A Welford, R S Morse: Fallout from 1957 and 1958 Nuclear Test Series. *Science* **134**, 980–984 (1961).
32. UNSCEAR-United Nations Scientific Committee on the Effects of Atomic Radiation: Ionizing Radiation: Levels and Effects. A Report to the General Assembly, Vol. 1, New York (1972).
33. H L Beck: Environmental Gamma Radiation from Deposited Fission Products, 1960–1964. *Health Physics* **12**, 313–322 (1966).

Bernd Franke can be reached either at the IFEU-Institut für Energie- und Umweltforschung Heidelberg e.V., Im Sand 5, 6900 Heidelberg I, the Federal Republic of Germany, or at the Institute for Energy and Environmental Research, 8520 Greenwood Ave., Takoma Park, Maryland 20912, U.S.A. Robert Alvarez is with the Environmental Policy Institute, 218 D Street S.E., Washington, D.C., 20003, U.S.A.

The CHAIRMAN. Thank you, Mr. Alverez.

We will turn to you, Dr. Johnson, at this point.

Dr. JOHNSON. I thank you, Senator Hatch, and the committee for your invitation last Friday to present testimony at this hearing, and your offer to provide transportation.

The questions considered by the committee about these tables are of great importance, and I have donated my time and other expenses to provide assistance.

I am one of a number of persons who have been critical of the radiation injury compensation tables. These dissident scientists include two Nobel Laureates—Dr. Linus Pauling and Dr. George Wald of Harvard—and Dr. Karl Morgan, who founded health physics; Dr. Alice Stewart, who founded the field of radiation epidemiology; and Drs. Everett Mendelsohn, John Gofman, Ernest Sternglass, Thomas Mancuso, Roland Finston, Donnel Borgman, Dorothy Legarreta, and Kathleen Tucker.

I strongly recommend that these scientists and the others also be invited to present their assessment of these compensation tables, since I cannot speak for them. They bring a different perspective than that expressed in the 1961 Atomic Energy Commission memo, which is appended to my written comments.

Although people in Utah had most serious injuries from the radioactive plumes and clouds that traveled across Utah——

The CHAIRMAN. If I can interrupt you for a second, we will be happy to keep the record open so they can submit statements for the record, and we will be happy to make them a part of the record, as long as they are reasonable statements, and not too voluminous.

Dr. JOHNSON. Thank you. Actually, they are appended to my written comments.

The CHAIRMAN. So we will just put them all in through your written statement; that will be fine.

Dr. JOHNSON. Thank you.

The nuclear bomb tests have actually been felt nationally, and indeed, in all countries of the world. A Nuclear Regulatory Commission memo estimates that cancer deaths due to worldwide fallout would range between 29,000 and 72,000, an excess incidence of 60,000 to 140,000 cases, and as many as 170,000 birth defects of all generations. These effects are not trivial.

Dr. Pauling believes these estimates are far too low. The point is that these problems are not restricted to Utah. The death of my aunt in Arizona from leukemia about 20 years ago, for example, may have been related to radioactive fallout.

Although the panel considered comparing exposed population data to regional cancer data, because of a wide variation in the regional cancer rates, they decided to compare exposed populations to U.S. rates.

Mormons, for example, could then have a 23 percent excess of cancer due to exposures to radioactive fallout, and could be represented as having no effects from the radiation exposure, since Utah Mormons have 23 percent less cancer than does the average U.S. population, despite their exposure to radioactive fallout since 1951.

The point is that healthy individuals and groups exposed to radiation will be penalized by these tables. The compensation tables are based on low-LET radiation like gamma rays. However, populations in the path of radioactive fallout have had exposure to fission and activation products, which are inhaled or ingested and stored in the body organs. I have figures and tables attached, which illustrate these points.

These exposures may be much more important than the gamma rays, since the ratio of beta radiation to gamma radiation may be as high as 100 to 1,000-to-1 in a fallout zone.

In addition, fallout contains important amounts of alpha radiation-emitting particulates. A person inhales about 20 cubic meters of air in a day, and so may inhale considerable amounts of alpha, beta, and gamma radiation emitting particulates in the air, which are then taken up in the blood and lymphatic circulations and stored in body organs.

International Radiation Protection Report ICRP-12 notes that personal air monitors show concentrations of radioactive particulates in air to be 100 to 1,000 times higher than stationary area air monitors. This is because the body is usually 30 degrees warmer than the surrounding air, and the warmed air between body and clothing rises. This thermal column brings contaminated particulates from surface dust on the ground or near the ground up to the head where it may be inhaled.

The importance of acute versus chronic doses of radiation over time was also not adequately considered. A recent paper in Nature reported that high-LET radiation at low doses over time was nine times more effective in inducing malignant transformations per rad than the same dose given as one dose. The effect was most pronounced at the smallest dose studied of 10 rads. They did not study smaller doses.

The panel members cite the 1980 BEIR report produced by the DOE-funded National Academy of Sciences and National Research Council. The latest research paper cited in that report was published in 1979, and as of January 1985, there have been more than 17,000 new publications, new reports on the causation of cancer since 1979. The 1980 BEIR report is already seriously outdated, and the same applies to these tables. However, in "Summary and Conclusions," page 137 of the BEIR report, BEIR 80 states, "Cancer may be induced by radiation in nearly all the tissues of the human body." Later, at page 211, BEIR 80 points out a relative risk of radiation-induced cancer of about 7.8 cases for each case of leukemia and bone cancer.

In other words, in a population exposed to radiation, for each case of radiation-induced leukemia, you could expect seven cases of other types of radiation-induced cancer. Of 24 persons with cancer suing the Department of Energy for damages in the fallout trial in Utah, the survivors of the 8 that contracted leukemia were awarded damages. In proportion to these 8 cases of radiation-induced leukemia, you could expect an additional 56 cases of cancer other than leukemia induced by nuclear fallout. Or, to use Dr. Jablon's example of 1,000 nuclear workers working 40 years with 5 rem exposures per year, and having 4.5 excess cases of radiation-induced leukemia, you could expect about 32 additional cases of radiation-induced cancer other than leukemia.

In contrast, the report of the compensation panel, or the working group, allows only three cases of radiation—induced cancer for each case of radiation-induced leukemia on page 76.

The panel has excluded a number of classes of cancer that must be included. They have excluded lymphoma, myeloma, cancer of skin, brain, ovary, testis, connective tissues, mesentery, mesothelium, larynx, nasal sinuses, parathyroid, and other organs.

To illustrate the diversity of cancers that can be induced by radiation, I cite one animal study of plutonium, which is appended, in which 38 percent developed seven different types of sarcomas with a median latency period of 1 year. Twenty-two percent developed mesothelioma, a type of cancer found in asbestos workers. The plutonium group had a cancer rate of 114.5 percent, since many animals had two different types of cancer. These include tumors of the kidney and mammary glands—47 percent of these animals with those tumors.

Plutonium, curium, americium and similar transuranics are extremely toxic. One teaspoon by way of illustration, of plutonium-238, will exceed the DOE limits for 40 billion nuclear workers, or 4 trillion people, and only 1 to 10 percent of this dose has been shown to cause a 33-percent increase in the rate of chromosome damage in nuclear workers.

In a study with dogs, 6 of 12 developed malignant melanoma after injection of a very small amount of radium 228, about 65-trillionths of a gram. Thorium-228 had similar effects. A pmr study of cancer incidence in plutonium workers at Rocky Flat in 1980 found an eight-fold excess of brain tumors and a threefold excess of malignant melanoma. This was an incidence study using a proportional morbidity ratio.

A pmr analysis of deaths in an early transuranium registry report disclosed a marked excess of cancer at very low doses.

An NCI-funded study of cancer incidence in Denver found an excess of 491 cases of cancer within isopleth areas contaminated with plutonium by Rocky Flats. Many classes of cancer were in excess; for example, you would expect 18 cancers of the testicle in this population—a rather uncommon tumor—and there were 42, in place of 18. There was about a 24-percent excess incidence of cancer of the ovary. There was an age-specific excess of 21.5 cases of leukemia in the population near the plant in the older age groups who would have been present in 1957 when an explosion at Rocky Flats blew out all 600-plus filters, loaded with plutonium, uranium, and other transuranics, since the filters had not been changed in 4 years of operation at this reprocessing plant.

Similarly, there was a wide variety of cancers found in excess in a study of cancer incidence in Utah, which was heavily contaminated with plutonium. Compared to a DOE-funded plutonium survey around the Savannah River plant, most of Utah has a soil concentration of plutonium more than 1,500 times greater than the background levels in South Carolina, exceeded only in a small area immediately around the SRP reactors. This implies high concentrations of plutonium in the air in Utah at times, much higher than the worldwide concentration as shown in figure 8.

The dry fallout that you would expect to find in an exhaust plume, and also which contaminated soil in areas around a nuclear point source, is only one-fifth as likely to be represented on this soil, since most of worldwide fallout represents wet fallout brought down by snow or rain.

How may we estimate the likelihood that persons with leukemia and cancer had developed cancer due to their radiation exposures? I maintain that because of differences in individual lifestyle and individual susceptibility to cancer, and many unknown factors about the degree of internal and external radiation exposure from alpha, beta, and gamma radiation-emitting radioisotopies, that it is not possible to develop tables of probable causation which are much more than doctrine. Whether any individual would have had cancer without prior exposure to radiation must be a matter to be decided in each individual case, after review of all the circumstances. The extent to which radiation was one of the important factors in the induction of a person's leukemia or cancer warrants a more thorough hearing than that afforded by reference to an arbitrary table.

The compensation panel believes that it is not possible to study cancer risk by looking at the variation in background radiation. In the BEIR–I report, the committee discusses the effects of exposure to radiation about twice natural background, that is, 170 millirems per year over a period of 30 years. The BEIR–I estimates that this dosage will cause an increase of 2 percent in cancer rates, about three-tenths-percent increase in birth defects, all generations, and an increase of 5 percent in nonspecific effects on health, due to increased susceptibility to disease, et cetera. This FRC/BEIR dose level, according to this estimate, will result in a 60-percent increase in cancer at a dose level of 5 rads per year, a 6-percent increase in birth defects, all generations, and a 150-percent increase in nonspecific effects on health, following the most widely accepted idea of a straight-line relationship between radiation exposure and effects on health.

However, the compensation panel uses the simple linear relationship only for cancer of breast and thyroid. For all other cancers, they use a linear-quadratic dose-effect model which projects that small doses of radiation have less effect per rad than do higher doses. This understates the effects of radiation at low doses and is a controversial assumption.

Recent work from Brookhaven National Laboratory published in Nature, as I mentioned, disclosed that the effects of high-LET radiation, like neutron and alpha radiation, are much more effective per rad at low doses.

The compensation panel or work study group uses a "wavelike" model to describe the risk of developing leukemia after radiation. This would not apply to the people in Utah that were exposed to radioactive fall-out on at least 28 different occasions through atmospheric tests over a period of 12 years, and then to ventings of radioactive plumes from underground nuclear tests on about a dozen other different occasions over the subsequent 20 years. These population exposures are quite different from the single external exposure at Hiroshima and Nagasaki, where you might see a wavelike model.

The most definitive study of the effects of ionizing radiation are those done of the effects on the most susceptible human subpopulation, the fetus and the embryo in utero. A single dose of about one-half rad from an abdominal x ray results in a doubling of the rates of childhood leukemia and cancer. That work was recently confirmed again.

The EPA has taken a leadership role in promulgating a Federal regulation to limit public population exposures to no more than 4 millirem per year from exposure to manmade beta and gamma radiation emitters in drinking water to prevent effects on health.

The CHAIRMAN. Excuse me, Dr. Johnson. Do you know how much longer you are going to take, because I have to go to this conference, and we have been going for about 35 minutes.

Dr. JOHNSON. Five or six minutes.

The CHAIRMAN. If you could——

Dr. JOHNSON. That is skipping over a large amount of this material.

The CHAIRMAN. I would like to finish now, or what I could do is come back at 2 o'clock, but I would prefer to get it done, if we can. Go ahead. If you could summarize, we will put the complete statement into the record. It is an exhaustive statement, and we will make it a complete part of the record, with the attachments thereto.

Go ahead.

Dr. JOHNSON. I will try to summarize very quickly, then.

The panel does not really address high-LET radiation except for exposure of radon and certain special cases. This has been an incredible position.

They rely on studies of Hiroshima and Nagasaki survivors which are a very special case, as already described.

They characterize global fall-out exposures as trivial. As I pointed out, they are not really trivial.

Among Japanese survivors, the death rate from leukemia peaked between 5 and 9 years after exposure to the bombs and declined thereafter. But because persons contracting leukemia may live for months to some years, the peak incidence from leukemia surely occurred in the first 2 years to 5 years after exposure. The same comment applies to the solid tumors. In other words, I feel that the minimum latent period has been misapplied in the tables; it is shorter.

The tables of relative risk of leukemia and cancer by age at the time of the bomb does not consider children less than 5 years of age or in utero, or adults greater than 60 years of age, even though the risk of induction of leukemia or cancer is increasing very sharply as you go toward the beginning of life and toward the end.

There is a most serious flaw in the concept that people can be treated as standardized units to which tables can be applied. This simply is not the case. Lifestyle, and many other factors, affect susceptibility to cancer and to radiation.

The compensation panel suggests that in utero exposures be treated no differently than postnatal exposures at age 8. This approach fails to consider the effect of age differences and the much greater susceptibility of the fetus to radiation.

The compensation panel notes that the incidence of lung cancer may vary by as much as a factor of 3 between regions, and yet they chose not to compare cancer rates in a region to that region.

The compensation panel lists 12 sources of uncertainty, and I will not read those because they are in the text, but very clearly, it is a very, very shakey foundation.

They address sources of uncertainty by such comments as "outside purview"; "the few known sex differentials are used"; "coefficients for younger ages, many of them were omitted"; "no adjustment made except for smoking." They concede that fewer PC values were obtainable for younger ages, and state "unknown" under effects of these various variables.

Among the oversight committee recommendations were that greater use be made of original radioepidemiologic data, and less of derived risk coefficients, less use of imaginative applications of higher mathematics, and more empirical observation, to cite another example of the issue of empirical versus doctrinal information.

In conclusion, there is a great urgency to generate doctrine on how much radiation will produce how many cancers in a population. In fact, it is not possible to do this; there is simply insufficient information. Much additional research must be done. Allowance must be made for great variation in susceptibility to radiation by age, sex, and between individuals, and for lifestyle and regional differences.

They relied on a mainstream line of opinion. This really refers to the individuals who have been aboard a great nuclear "gravy train" for the past 20, 30, or more years.

I maintain that the compensation panel should meet the same test as that applied for jury members who serve on a jury to hear radiation compensation cases. They must be able to meet the same tests of objectivity as a jury panel.

They have excluded important types of cancer. I have gone over those already. I also believe the stage has been set with the tables for further fudging of estimates of population dosage. Actual measurements of radiation taken during the passage of the radioactive plumes and clouds after nuclear bomb blasts must be given greater weight than estimates made 25 to 40 years after, based on dubious chains of assumptions. The use of soil samples or bricks will not be very helpful. A brick does not inhale 8,000 cubic meters of dusty air in a year, as does a man. A brick does not drink 200 gallons of water or eat half a ton of food, and a brick does not form organs, grow, develop and reproduce, or live 80 years.

I believe that the willingness of the panel members to accept positions on the panel in view of their backgrounds is a disservice to the taxpayers and a waste of tax dollars; beyond that, a disservice to the thousands of children, women and men who have suffered and died as a result of exposure to radioactive plumes and clouds from nuclear bomb tests.

I am equally critical of the key personnel in positions of public trust and confidence who have remained silent over the years, or even acted in complicity with the nuclear establishment, in exchange for annual renewal of their research funds, or for job security and personal advancement. These persons who have been aboard this great "nuclear gravy train" should not be placed in charge of deciding exactly how much injury they have permitted to children, women and men exposed to radioactive fallout over the years.

I recommend that to answer the many important questions still unanswered, that research must be done, and it should be designed and carried out by aggressive, able scientists motivated by public interest, who should not have any prior, present or anticipated association with the nuclear establishment and their friends. They should be able to qualify as jurors to hear radiation compensation cases. This is a very suitable test in this very sensitive area.

There should be a series of public hearings on the composition of the NIH working group compensation panel, and of the National Academy of Sciences oversight committee, including members like Gene Saenger, Jakob Fabricant, and others, and to provide for a thorough public airing of the proposed compensation tables. These hearings should be well-publicized in advance, and they should be held in St. George, and in Salt Lake City, as well as in Washington, DC. And I am glad to hear that additional written and oral comments may be received in relation to the hearing on this issue.

I thank you.

The CHAIRMAN. Thank you, Dr. Johnson.

[The prepared statement of Dr. Johnson and responses to questions submitted by Senator Simpson follow:]

June 11, 1985

Senate Hearing on the Radiation Injury Compensation Tables
Testimony of Carl J. Johnson, M.D.,M.P.H.*

I thank the Committee for their invitation last Friday to present testimony at this hearing and their offer to provide transportation. The questions considered by the Committee about these tables are of great importance, and I have donated my time and other expenses to provide assistance.

I am one of a number of persons who have been critical of the radiation injury compensation tables. These include two Nobel Laureates, Dr. Linus Pauling and Dr. George Wald of Harvard; and Dr. Karl Morgan, who founded health physics, Dr. Alice Stewart, who founded the field of radiation epidemiology, and Drs. Everett Mendelsohn, John Gofman, Ernest Sternglass, Thomas Mancuso, Roland Finston, Donnel Borgman, Dorothy Legarreta and Kathleen Tucker (App.1-9)

There must be a fair, equitable and balanced hearing, and I strongly recommend that these scientists and others who have critiqued these compensation tables also be invited to present you with their assessment of these compensation tables, since I cannot speak for them. They bring a different perspective than that expressed in a 1962 Atomic Energy Commission memo (App. 10).

Although people in Utah had most serious injuries from the radioactive plumes and clouds that traveled across Utah from nuclear bomb explosions at the Nevada Test Site, the effects have actually been felt nationally, and indeed, in all countries of the world. A Nuclear Regulatory Commission memo estimates that cancer deaths due to world-wide fallout would range between 29,000 and 72,000 (an excess incidence of 60,000 to 140,000), and as many as 170,000 birth defects. Dr. Pauling believes these estimates are far too low. The point is that these problems are not restricted to Utah.

* 42 Hillside Drive, Denver, Colorado 80215 (303) 232-2328

Members of the National Institutes of Health (NIH) Ad Hoc Working Group to Develop Radioepidemiological Tables, really a compensation panel for the public, have taken positions that would deny compensation to those suffering injury from radioactive fallout. Members of the compensation panel would not qualify as members of a jury to hear a case involving compensation for injury by radiation. The same comment would apply to some of the members of the Oversight Committee.

There are thousands of people suing the nuclear industry and nuclear agencies for injuries from radiation exposure. The nuclear establishment represents investments greater than one trillion dollars, and has much more to lose from injury litigation than the tobacco, chemical and the asbestos industries. The tobacco industry still hires scientists who claim no effect from tobacco. The president of Johns Mansville, informed in 1935 that asbestos was causing cancer, ordered the offending report locked up in the corporate safe. It was found later in discovery proceedings after about 50 years.

The nuclear industry position is illustrated in an Atomic Energy Commission memo (App. 10) on how to study radiation effects. Quote, "the basic approach would be to start with a simple, straightforward statement of conclusions. We would then identify the major questions that could be expected to be asked in connection with these conclusions. It would be a straightforward matter to select the key scientific consultants (emphasis added) whose opinion should be sought in order to substantiate the validity of the conclusions or recommend appropriate modifications".

In my opinion, these "key scientific consultants" have been selected for the NIH working group to develop compensation tables for radiation victims.

One, a former Director of the National Cancer Institute, was previously an officer with the Atomic Energy Commission, hardly an appropriate background for the dominant position in the National

Cancer Institute. He and two other members provided testimony for the Department of Energy (DOE) against persons who had died from leukemia and cancer from radioactive fallout, in the fallout trials in Salt Lake City. The judge was not convinced by their testimony against the plaintiffs. Two other members have also been affiliated with the AtomicEnergy Commission. A National Cancer Institute statistician member is a notorious critic of any studies which find radiation effects, and is one of those who testified against the plaintiffs in the fallout trial. Another is also a critic of radiation studies which find radiation effects, and provided testimony for the Department of Energy against the plaintiffs.

Two members are associated with the National Academy of Sciences and the National Research Council. These agencies are dependent on research grants from the Department of Energy. The compensation panel boasts a person who won a Nobel prize. However, her work was not in the area of health effects research. She informs the public that radiation is beneficial to health. She has admitted that she is not an expert in the field of radiation effects. Yet, she said for the record, in Salt Lake City, in reference to the fallout victims in Utah, that there "was no basis for any of the claims".

There is some evidence that the National Cancer Institute has fallen into an advocacy position, with the effect of defending sister federal agencies and the nuclear industry against thousands of potential lawsuits brought by populations and workers injured by exposures to radiation. Where are the scientists in the National Cancer Institute, or in any of the NIH institutes, who have aggressively critiqued current radiation guidelines and standards, or who have vigorously supported or pursued studies of radiation effects in workers or in populations near nuclear installations? The involvement of present and former National Institute officers on the compensation panel detracts from its credibility.

As an illustration of NCI bias, an NCI statistician has had a series of publications which purport to show no effect from radioactive fallout.

He testifies against plaintiffs in Salt Lake City at the fallout trial, and then is selected to serve on the NIH compensation panel, which is to have a key role in determining compensation for fallout victims.

As a second illustration, another National Cancer Institute officer drafts a biased appraisal of a cohort study of cancer incidence which compares a Mormon population in southern Utah to all Utah Mormons. The N.C.I. text has important factual errors, all of which detract from the value of the Mormon fallout study. The principal investigator of the study calls the National Cancer Institute officer to point out the factual errors, and to complain about the derogatory characterizations. However, the report is published without correction (app. 11-14).

One member of the compensation panel gave a paper in Los Angeles last week on these proposed tables at a meeting on the topic "Causation and Compensation for Alleged Victims of Nuclear Testing and Other Exposures". This member said that the compensation tables were based in large part on the survivor data from Japan. The survivors of Hiroshima and Nagasaki had only one acute exposure to penetrating radiation, and they had no exposure to radioactive fallout. The Japanese study is flawed because it is a study of hardy survivors still alive five years after their single exposure. Many thousands of people exposed to radiation died before the study team began their work. Estimates of radiation exposure of the Japanese are now expected to be reduced by half, resulting in a doubling of the estimates of radiation effects per rad, some 40 years after the bomb, and after 35 years of study.

Further, the incidence of leukemia and of many types of cancer among the Japanese is not the same as among the Mormons of Utah. There are concerns about objectivity of the study team at Hiroshima and Nagasaki, and about their methods, and I believe we should be concerned that members of the flawed survivor study team are on the NIH compensation panel.

Although the compensation panel considered comparing exposed population data to regional cancer data because of wide variation in regional cancer rates, it was decided to compare exposed populations to U.S. rates. Mormons could then have a 23% excess of cancer due to exposures to radioactive fallout, and could be represented as having no effect from radiation, since Utah Mormons have 23% less cancer than does the average U.S. population, despite exposures to radioactive fallout since 1951. Healthy individuals and groups exposed to radiation will be penalized.

Further, the compensation tables are based on low linear energy transfer (LET) radiation like x-rays or gamma rays. However, populations in the path of plumes and clouds of radioactive fallout have had exposures to internal body burdens of fission products and radioactive activation products which are inhaled or ingested and stored in body organs (figures 1, 2; table 1). These exposures may be much more important than the gamma rays, since the ratio of beta radiation to gamma radiation may be as high as 100 to 1,000 to one. In addition, fallout contains important amounts of alpha-radiation-emitting particulates. A person inhales about 20 cubic meters of air in a day, and so may inhale considerable amounts of alpha, beta, gamma and neutron-emitting radioactive particulates in air, which are then taken up in the blood and lymphatic circulations and stored in body organs (figures 3-5).

An international radiation protection report, ICRP 12, notes that personal air monitors show concentrations of radioactive particulates in air to be 100 to 1,000 times higher than stationary area air monitors (app. 15). This is because the body is usually 30° warmer than the surrounding air, and the warmed air between body and clothing rises. This thermal column brings contaminated particulates from surface dust on the ground or near the ground up to the head where it may be inhaled.

Dr. Jablon conceded that such considerations are a problem, and also that there are problems in relying on Japanese data. He noted that the Japanese studies are now being redone and that the health effects per rad may increase by two.

The importance of acute vs. chronic doses of low level radiation over time was also not adequately considered. A recent paper in Nature reported that high linear energy transfer (LET) radiation at low doses over time was nine times more effective in inducing malignant transformations per rad than the same dose given as one dose. The effect was most pronounced at the smallest dose studied of 10 rads (app. 16).

The compensation panel members like to cite the 1980 BEIR report produced by the DOE-funded National Academy of Science and National Research Council. The latest research paper cited in that report was published in 1979, and as of January, 1985, there had been more than 17,000 new publications on the causation of cancer since 1979. The 1980 BEIR report is already seriously outdated. However, it is still a useful reference.

In "Summary and Conclusions" (Somatic Effects: Cancer, p.137), BEIR 80 states "Cancer may be induced by radiation in nearly all the tissues of the human body." Later (p.211) BEIR 80 points out a relative risk of radiation-induced cancer of 7.5-8.1 (7.8) cases for each case of leukemia or bone cancer (there are fewer cases of bone cancer, about one case for each 9-10 cases of leukemia).

In other words, in a population exposed to radiation, for each case of radiation-induced leukemia, you could expect seven cases of other types of radiation-induced cancer. Of 24 persons with cancer suing the DOE for damages in the fallout trial, the survivors of the eight who had contracted leukemia were awarded damages. In proportion to those eight cases of radiation-induced leukemia, you could expect an additional 56 cases of cancer other than leukemia induced by nuclear fallout.

In contrast, the Report of the NIH Ad Hoc Working Group (the compensation panel) allows only three cases of radiation-induced cancer for each case of radiation-induced leukemia (p.76).

The NIH Working group has excluded (p. 262) a number of classes of cancer that must be included. They have excluded lymphoma, myeloma, cancer of skin, brain, ovary, testes, connective tissues, mesentery, mesothelium, larynx, nasal sinuses, parathyroid and other organs.

To illustrate the diversity of cancers that can be induced by radiation, I cite one animal study of plutonium in which 38% developed seven different types of sarcomas with a median latency period of one year (app. 17). Twenty-two percent developed mesothelioma, a type of cancer found in asbestos workers. The plutonium group had a cancer rate of 114.5%, since many animals had two different types of cancer. These include tumors of the kidney and mammary glands (47%). Plutonium, curium, americium and similar transuranics are extremely toxic (app. 18, 19). One teaspoon of plutonium 238 will exceed the DOE limits for 40 billion nuclear workers or four trillion people, and only 1-10% of this dose has been shown to cause a 33% increase in the rate of chromosome damage in nuclear workers (fig.5).

In a study with dogs, six of 12 developed malignant melanoma after injection of a very small amount of radium 228. Thorium 228 had similar effects. A pmr study of cancer incidence in plutonium workers at Rocky Flats in 1980 found an eight-fold excess of brain tumors and a three-fold excess of malignant melanoma (app. 20, 21). A pmr analysis of deaths in an early Transuranium Registry report disclosed a marked excess of cancer at very low doses (tables 2, 3).

An NCI-funded study of cancer incidence in Denver found an excess of 491 cases of cancer within isopleth areas contaminated with plutonium by Rocky Flats (app. 22,23). Many classes of cancer were in excess, i.e., 18 cancers of the testicle were expected, 42 occurred. There was about a 24% excess incidence of cancer of the ovary. There was an age-specific excess of 21.5 cases of leukemia in the area near the plant in older age groups (1969-1971).

Similarly, there were a wide variety of cancers found in excess in a study of cancer incidence in Utah, which was heavily contaminated with plutonium (figure 6). Compared to a DOE-funded plutonium survey around the Savannah River Plant (SRP)(figure 7), most of Utah has a soil concentration of plutonium more than 1500 times greater than the background levels in South Carolina, exceeded only in a small area immediately around the SRP reactors. This implies high concentrations of plutonium in the air in Utah at times, much higher than the world-wide concentrations shown in figure 8.

Specific Comments

Public Law 97-414 became law on 1-4-83 with the purpose to amend the Federal Food, Drug and Cosmetic Act to facilitate the development of drugs for rare diseases and conditions, etc. Section 7(b) directed the Secretary of HHS to "devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such diseases, have developed cancer as a result of those radiation doses".

How may we estimate the likelihood that persons with leukemia and cancer had developed cancer due to their radiation exposures? I maintain that, because of differences in individual life style and individual susceptibility to cancer, and many unknown factors about the degree of radiation exposure (internal and external) from alpha, beta, and gamma radiation-emitting radioisotopes, that it is not possible to develop tables of probable causation which are much more than doctrine. Whether any individual would have had cancer without prior exposure to radiation must be a matter to be decided in each individual case, after review of all the circumstances. The extent to which radiation was one of the important factors in the induction of a person's leukemia or cancer warrants a more thorough hearing than that afforded by reference to an arbitrary table.

The Working Group, perhaps better identified as the compensation panel, based most of their risk coefficients on the National Academy of Science (NAS) BEIR III report (of 78 age, sex-and site-specific risk coefficients, 40 came from the BEIR III report, and 38 came from more recent sources). The compensation panel and the oversight committee agreed on some of the problems which bring the value of these risk coefficients into question. They believe that these can be resolved in the future through the accumulation of more human data, by new insights into carcinogenesis, and by less reliance on mathematical ingenuity, and acknowledge that considerable judgement or discretion would be exercised in dealing with the "scientific uncertainties".

Ionizing radiation was discovered ninety years ago and only 75-80 years ago did we learn that it caused skin cancer and leukemia. The first international recommendation for radiation protection came less than 60 years ago, from the International Congress for Radiology, an organization of individuals whose livelihood came from exposing people to radiation. Over the past sixty years, we have seen a dramatic decrease in the dosage of radiation considered to be safe. Consistent throughout has been the influence on development of radiation guidelines and standards by those involved in occupations utilizing radiation.

I. In constructing the radioepidemiological tables, perhaps better known as radiation injury compensation tables, the compensation panel relied principally on the 1980 BEIR report, utilizing human epidemiologic data, and studies of effects of radiation on animals (principally rodents) and on the malignant transformation of cell cultures.

II. The compensation panel cites a number of official reports on radiation injury, and notes that, while effects of moderate to high radiation doses on large populations can be estimated, there is greater uncertainty about the carcinogenic effects of low doses of radiation. For example, the BEIR III committee was unwilling to make estimates of carcinogenic effects of radiation for acute doses below ten rads, or for continuing exposures to doses below one rad per year. The panel states "the nonthreshold hypothesis is accepted for radiation protection purposes", that is, radiation will have carcinogenic effects on cells, animals and man at any dose level, no matter how small, in some proportion to the dose.

The panel cites natural background radiation, which they say ranges from 80 -200 millirem (mrem) per year in the United States. According to an EPA report (EPA-ORP/SID 72-1) the average dose equivalent from terrestrial and cosmic radiation to the U.S. population is 84 millirem per year. This ranges from 65 millirem per year in the coastal plain to 165 millirem per year in the Denver area.

Based on background radiation doses to bone marrow, internal radiation from radionuclides stored in body organs account for about 15 millirem per year; 13 from potassium 40, and 2 millirem per year from other radionuclides, including carbon $_{14}$, rubidium 87 and four alpha radiation emitters, radium 226 and 228, polonium 216 and radon 222.

The compensation panel believes that it is not possible to study cancer risk by looking at the variation in natural background, but that it is possible to extrapolate from higher levels of radiation dosage, where effects have been observed. In the BEIR I report, the committee discusses the effects of exposure to radiation about twice natural background, that is, 170 millirem per year over a period of thirty years. This is the Federal Radiation Council limit for exposures to the general population. The BEIR I committee estimates that this dosage will cause an increase of 2% in cancer rates, about 0.3% increase in birth defects, all generations, and an increase of 5% in nonspecific effects on health, due to increased susceptibility to disease, etc. This FRC/BEIR dose level, according to this estimate, will result in a 60% increase in cancer at a dose level of 5 rads per year, a 6% increase in birth defects, all generations, and a 150% increase in nonspecific effects on health, following the most widely accepted idea of a straight line relationship between radiation exposure and effects on health.

However, the compensation panel uses the simple linear relationship only for cancer of breast and thyroid. For all other cancers, they use a linear-quadratic dose-effect model based on two constants, which predict that small doses of radiation have less effect per rad than do higher doses. This understates the effects of radiation at low doses and is a controversial assumption. Recent work from Brookhaven National Laboratory published in Nature, disclosed that the effects of high linear energy transfer radiation, like neutron and alpha radiation, are much more effective per rad at low doses, at low dose rates.than high doses. At the lowest dose studied, 10 rads induced nine times more malignant transformations per rad when administered over time than when given in a single dose.

III. The compensation panel discusses the effect of dose rates and notes that one of the studies on which they relied heavily, that of the Japanese survivors, involved a high dose rate, i.e. one acute exposure. They cite contradictory evidence, namely, that the linear dose effect model fits the experience of persons contracting cancer of breast and thyroid, but state that for other cancer sites the low LET radiation is less carcinogenic at a low dose rate. But perhaps this is just because there has not been adequate study of cancers other than the common breast and thyroid cancers.

IV. The panel discusses two models for calculation of probability of causation (PC) values. The absolute risk model assumes that the radiation-induced risk of developing cancer is constant after a suitable latent period following irradiation. The relative risk time projection model states that at any time after a latent period the given dose of radiation increases the probability of developing cancer by a constant fraction of the base line risk. The data, especially on breast and lung cancer in Japanese survivors, support the relative risk time projection model more convincingly, and I agree with compensation panel's use of this model.

The compensation panel uses a wave-length model to describe the risk of developing leukemia after radiation. I think care must be used here in applying this wave-like model to populations who have had exposures to internal deposits of radionuclides and to environmental contamination over a period of time. The people in Utah, for example, were exposed to radioactive fallout on at least 28 different occasions through atmospheric tests over a period of 12 years (1951-1962), and then to ventings of radioactive plumes from underground nuclear tests on at least 13 other different occasions over the subsequent 20 years. These population exposures are quite different from those sustained at Hiroshima and Nagasaki.

The most definitive study of the effects of ionizing radiation are those done of the effects on the most susceptible human subpopulation, the fetus and the embryo in utero. A single dose of about 500 millirem from an abdominal x-ray results in a doubling of the rates of childhood leukemia and cancer. That work was recently confirmed again in a study of twins reported in the New England Jounal of Medicine.

The EPA has taken a leadership role in promulgating a federal regulation to limit public population exposures to no more than 4 millirem per year from exposure to man-made beta and gamma radiation emitters in drinking water. This protective regulation contrasts sharply to a notorious omission of uranium from the EPA water quality regulations, until 1979. The EPA also has a guideline limiting population exposures to no more than 25 millirems per year around nuclear facilities, because of concerns about effects on health.

V. The panel considers neutron and alpha radiation, the so-called high LET radiation, and concedes that this radiation "appears to be more effective in causing cancers" than gamma rays. In fact, it is widely accepted today that alpha radiation is 20 times more injurious per rad than gamma radiation. One rad of gamma radiation equals one rem, one rad of neutron radiation equals 10 rem, and one rad of alpha radiation equals 20 rem. There is now evidence that at low dose rates, one rad of neutron or alpha radiation may actually have an effect nine to ten times greater, that is, one rad of alpha radiation may be equivalent to 90-100 rem.

Each disintegration of an alpha radiation-emitting atom, like plutonium, will penetrate as many as five or more cells. This single alpha ray will induce doses within the nuclei of cells of 2,000 rem, and thus, each single ray will kill or seriously injure about five cells. The badly-injured cells that survive undergo poor repair of the damaged DNA, and are more likely to undergo malignant transformation than are cells injured by gamma or beta radiation.

The compensation panel does not really address these questions. They state that all of their tables, except for bone and lung cancer after exposure to radon (uranium miners) deal with low LET radiation. This is an incredible position. The compensation panel mentions that estimates of probability of causation have been prepared by others, such as Gofman, Stewart and British Nuclear Fuels. However, they cite reasons why they cannot use these other estimates.

A few comments must be made about the studies of Hiroshima and Nagasaki survivors. The compensation panel cites no increase in cancer deaths among 23,073 survivors exposed to 1-9 rads (1950-1978).

but an increase of 54% for the 6,035 survivors in the life span sample exposed to 100 or more rads (498 cancer deaths observed, 323 deaths expected). An increase of 175 cancer deaths in this high exposure group indicates an increase in cancer cases of about 350, since only about one-half of persons contracting cancer die of cancer. A serious flaw with these studies is that they did not begin until five years after the bomb had dropped. There were thousands of deaths of people after the acute exposure to nuclear radiation from these nuclear blasts who could not be included in these survivor studies. The survivors indeed survived the acute effects of the bomb and were still around in 1950 (p.13).

The compensation panel states that the doses from global fallout is negligibly small (p.15). However, an NRC memo estimates 29,000-72,000 cancer deaths (an excess incidence of perhaps 140,000) and as many as 170,000 birth defects, all generations.

It is conceded that leukemia and bone cancer have periods of short latency. Among the Japanese survivors the death rate from leukemia peaked between 5 and 9 years after exposure to the bombs and declined slowly thereafter. Because persons contracting leukemia may live for months to some years after contracting their disease, the peak incidence from leukemia surely occurred in the first 2 to 5 years after their acute exposure to the bomb.

Among the survivors, the first sharp increase in cancer deaths, other than leukemia, occurred between 10 to 14 years after exposure, steadily rising afterward, and then, after 27 years, rising very sharply, accelerating by 2.4 times between 27 and 32 years. The first sharp increase in deaths 10 to 14 years after the bomb indicates that the first sharp increase in cancer incidence occurred between five and nine years after exposure. However, the compensation panel states (p.20) "the first 10 years after exposure were ignored in the risk calculations". A so-called " minimum response"time was assumed.

Tables of relative risk of leukemia and cancer by age at time of the bomb, on pages 39-41, do not consider children less than 5 years of age or in utero, or adults greater than 60 years of age, even though the risk of induction of leukemia or cancer is increasing very sharply at the beginning of the life span for leukemia and cancer; and for cancer toward the end of the life span.

In chapter 4, on pages 42, 43 and after, the compensation panel addresses the limitations of the concept that tables of probability of causation may be developed. In fact, this concept assumes that every individual may be described in terms of age, sex, smoking habits, and perhaps one or two other very simple categories. However, there are a large number of individual variables that determine susceptibility to cancer, and the likelihood that a certain dose ofradiation will be an important factor in induction of leukemia or cancer.

There is a most serious basic flaw in this concept. There has been no standardization of people. People are simply not uniform or standard individuals. They are not like packaged products as in a supermarket, and are not produced in production lines. This is especially true in the case of individual susceptibility to cancer and to the effects of radiation.

The basic concept responsible for the creation of the compensation panel and their compensation tables, if carried further, would obviate the need for courts and attorneys, and for public hearings. All issues could be reduced to federal standards, forms and tables, which would determine, according to mathematical formulae, whether there had been injury and liability, and whether compensation was due, and if so, how much. The tables are fatally flawed because they are based entirely on this false premise. This simplistic concept might well have been designed by attorneys for the defense of the Department of Energy and other federal agencies and their corporate contractors, and, if implemented, will result in gross injustice to people injured by radiation from the radioactive contaminants released by nuclear facilities.

The compensation panel (p.61) does not explicitly include the Oxford survey area estimates in its tabulated estimates of lifetime risk following acute and chronic exposures to radiation. The Oxford Survey indicated a risk of 25 excess leukemia deaths and 20 excess deaths from other cancers per million persons per year per rad for the first 12 and 10 years of life, respectively. The compensation panel instead suggests that in utero exposures be treated no differently than post-natal exposures at age 0. This approach fails to consider the effect of age differences, and the much greater susceptibility of the fetus to radiation.

The President wisely states (cited on p. 79) that "there is as yet no consensus among radiation experts in relating human cancers and exposure to low levels of radiation" and he directs "the Secretary of Health and Human Services to "assess the credibility, validity, and degree of uncertainty associated with such tables".

In Chapter 5, the compensation panel describes their calculation of the probability of causation for leukemia and cancers of bone and joint, thyroid, breast, lung, esophagus, stomach, colon, liver, pancreas, kidney, bladder and salivary glands.

The compensation panel notes that the incidence of lung cancer may vary by as much as a factor of three between regions (p.81, tables VII-2). Leukemia rates in males ranged from 8.1 per 100,000 (New Mexico) to 12.0 (Detroit) and for females, from 4.9 (New Mexico) to 6.1 (Hawaii and Connecticut). A number of cancer sites for both men and women are more than twice as high as the national rates, and a number of cancer sites in other regions are less than half the national rates (p.105).

The compensation panel cites the BEIR III report of a minimal latent period of 2 to 4 years between exposure and tumor detection for leukemia and bone cancer. However, data from Nagasaki and Hiroshima indicates that this should represent the mean period of cancer induction, since themaximum death rate from leukemia occurred 5-9 years after the bomb.

The compensation panel cites the BEIR III minimal latent period of 10 years for solid tumors. This also is inconsistent with the Japanese data, which indicated a sharp increase above expected rates of solid tumor deaths 10 to 14 years after the bomb, implying a sharp increase in cancer incidence 5-to 9 years after exposure.

On page 82, the panel notes minimal latent periods for bone cancer and leukemia of 1.5 and two years, respectively. However, there is a range of uncertainty of 1-4 years, which makes the possible minimal latent period for these two tumors very short indeed. The compensation panel assumed that the full expression of increased relative risk for solid cancers to occur as early as 10 years after exposure, and that the increased risk builds up at intervals of 5 to 9 years after exposure, but they do not appear to have calculated a range of uncertainty for these estimates.

The compensation panel lists 12 sources of uncertainty on pp. 109-110: The dose to the individual, the source tables on cancer incidence, the influence of age at time of exposure, sex differences, cancer sites and cell types, minimal latent period, risk coefficients, dosimetry and epidemiological studies, dose-response functions, dose rate, time-response model and other risk factors.

They address these sources of uncertainty by such resolutions as "outside purview of working group", "many coefficients for younger ages omitted", "the few known sex differentials are used" (i.e., more breast and thyroid cancers per rad in women and less leukemia), "by excluding lymphoma, myeloma,by establishing a minimum latency period of two years for leukemia and bone cancer" and "smoothed 5 to 10 years years (latency period) for solid" (cancers), and "no adjustment made (for other risk factors) except for smoking".

They acknowledge that the practical effect on their probability of causation calculations to be "highly variable, expecially if unbadged", "without further adjustment for ethnic and regional differences, PC values may be high or low" and "ignoring changes and incidence over time affects some PC's for early onset of certain cancers". They concede "fewer PC values obtainable for younger ages", "PC's for exposure after age 65 especially uncertain" and "unknown" and "exclusion makes PC approach inapplicable, inclusion may provide wrong guidance" and "there will be fewer zero PC values within 10 years of exposure". "Essential statistical uncertainty carried forward into PC calculations". "A-bomb revision may increase many risk coefficients by a factor of 1.2 -2.2 and PC values somewhat less". "The true PC may be greater or less depending on the actual form of the dose-response function ". "PC's calculated at less than 2% may be too large or too small, but not more than a factor of 2.5; PC's of 5-20 % by not more than a factor of 2; and larger PC's by lesser amounts", and for "other risk factors" the practical effect is "unknown and depending on any interaction with radiation".

On pp. 113-115, tables present limits of a 90% credibility interval and the effect on PC, and the values of the PC for which a 95% lower credibility limit is 50%.

The National Academy of Sciences (NAS) oversight committee commented on an earlier draft (July 1984) and the compensation panel (NIH Working Group) has made responses (p. 339-344). The panel states (p.339) that chronic lymphatic leukemia (CLL) is the only major type of leukemia that has not been observed to increase in incidence in irradiated populations. In fact, CLL has been reported to be significantly increased in a population with heavy exposures to diagnostic radiation.

The panel admits the previous BEIR position and states "it may well be that all tissues in which cancers arise are susceptable to the carcinogenic effect of ionizing radiation", but qualify this, saying this has not been demonstrated. They employed three criteria in selecting sites for compensation, omitting a number of classes of cancer where they believed there had been insufficient study and data.

The oversight committee recommended that greater use be made of original radioepidemiological data, and less use of derived risk coefficients. the oversight committee recommended that the available statistics be reanalyzed on excess cancer to model time dependence without specific assumptions about period of latency, rather than assuming a fixed minimum latency period. A number of the recommendations received the response "for the future" from the compensation panel, and are not reflected in the present report.

The oversight committee recommended that "a method for estimating assigned shares for persons exposed to high LET radiation be developed that does not depend so heavily on estimates for low LET radiation". The compensation panel abandoned the use of quality factors for estimating cancer risk from high LET radiation, and limited its consideration to exposures of bone to radium 224, and lung to radon daughters. The oversight committee felt that dose rates need to be further investigated and considered, and recommended that the working group conduct a quantitative appraisal"such as a sensitivity analysis, to evaluate the uncertainties in the assumptions, data, and methods used in constructing the tables, the influence on the reliability of the tables of assigned shares, and their implication for possible uses of the tables".

CONCLUSION

There was a clear indication at the Los Angeles meeting of the AAAS on radiation injury compensation that there is a great urgency to generate concrete doctrine on how much radiation will produce how many cancers in a population. In fact, it is not possible to do this. There is simply insufficient information. Much additional research must be done. Allowance must be made for great variation in susceptibility to radiation by age, sex, and between individuals. Corrections must be made for differences in lifestyle that affect cancer rates, and for regional differences. Each person must be evaluated individually, and not submitted to an arbitrary, rigid, simplistic doctrinal formula devised by friends of the nuclear industry.

The compensation panel relies on a mainstream line of opinion on effects of radiation. This "mainstream" consists of agency, industry and medical school personnel who have made their careers within the nuclear establishment, or who have received its research support. These people have been aboard a great nuclear gravy train, for 20, 30 years or more. This train has been fueled by hundreds of billions of tax dollars over the past 40 years.

Two of the agencies that generate "mainstream opinion" (actually doctrine), the National Council on Radiation Protection and the International Commission on Radiological Protection, are quasi-official self-selected bodies, principally representing industrial interests. They do not ask for public input, do not have public hearings, do not seek public review of their proclamations. They do not develop standards, but guidelines, since they have insufficient evidence and no authority to produce standards. They act as if they were ecclesiastical bodies, with the task of promulgating non-medical doctrine on radiation risks to health, and give great weight to the need to protect the interests of the nuclear industry. The NIH Working Group (compensation panel) assembled to develop the radioepidemiologic (compensation) tables is quite similar in composition and purpose, in my opinion. Although the compensation panel have developed "compensation" tables, in fact, their purpose is to deny compensation to many who have contracted cancer resulting from exposure to radioactive fallout or other radiation source. Persons contracting many important types of cancer shown to be caused by radiation, such as lymphoma, myeloma, cancer of upper respiratory tract, gonads, mesentery, mesothelium, connective tissue, and skin will be denied compensation by the compensation panel and their "compensation tables". The risks estimated of contracting leukemia and other "allowable" cancers are unreasonably low for the fetus, the child and the aged.

Further fudging will occur with estimates of population doses, as former AEC personnel (now with DOE, NRC, and the Office of Radiation Programs of the EPA, and even officials of the National Cancer Institute) try to construct dose data from measurements of soil samples and bricks 25 to 40 years after the bombs ("Trinity" in 1945 was a very dirty nuclear bomb).

Actual measurements of radiation taken during the passage of the radioactive plumes and clouds after nuclear bomb blasts must be given greater weight than estimates made 25 to 40 years after, based on dubious chains of assumptions. The use of soil samples or bricks will not be very helpful. A brick does not inhale 8000 cubic meters of dusty air in a year, as does a man. A brick does not drink 200 gallons of water, or eat half a ton of food, and a brick does form organs, grow, develop and reproduce, or live 80 years.

The compensation panel members could not pass the conflict of interest tests in the selection of a panel of jurors to hear a radiation compensation case. The selection of an obviously biased panel has resulted in these seriously flawed, inadequate and unjust tables, which protect the DOE and its corporate contractors. This has been a public disservice and a waste of tax dollars. Beyond that, it is a disservice to the thousands of children, women and men who have suffered and died as a result of exposure to radioactive plumes and clouds from nuclear bomb tests. Equally guilty are those key personnel in positions of public trust and confidence who have remained silent over the years, or even acted in complicity with the nuclear establishment, in exchange for annual renewal of their research funds, or for job security and personal advancement. Those persons who have been riding the great nuclear gravy train for the past 10, 20, 30 or more years should not be placed in charge of deciding exactly how much injury they have permitted to children, women and men exposed to radioactive fallout over the years.

To answer the many important questions still unanswered, the research that must be done should be designed and carried out by aggressive, able scientists motivated by public interest, who should not have any prior, present or anticipated association with the nuclear establishment and their friends. They should be able to qualify as jurors to hear radiation compensation cases.

There should be a series of public hearings on the composition of the NIH Working Group (compensation panel) and of the National Academy of Science oversight committee (Eugene L. Saenger, Jakob I. Fabricant, et al), and to provide for a thorough public airing of the proposed radioepidemiologic (compensation) tables. These hearings should be well publicised in advance, and they should be held in St. George, and in Salt Lake City, as well as in Washington, D.C. Written and oral critical comment should be solicited and supported. At the conclusion of the hearings, a new and more appropriate course of action should be developed by the congressional delegation and the appropriate congressional committees.

Table 1

Plutonium concentrations in organs of nuclear plant workers in picocuries* per kilogram (pCi/kg)**

	Worker A	Worker B	Worker C	Other
Total plutonium in body, pCi	42,800	270	42,200	--
Estimated exposure period	15 years	16 years	17 years	--
Type of exposure	chronic inhalation	chronic inhalation	acute inhalation	--
	pCi/kg	pCi/kg	pCi/kg	% of total
Skin	n/a	n/a	42	0.2%
Trachea and larynx	34	n/a	n/a	--
Lung	21,888	1.4	23	--
Tracheo-bronchial lymph nodes	342,000	31	756	--
Liver	3,762	171	6,300	--
Bone	718	8.6	1,386	--
Brain	n/a	0.1	n/a	--
Brain stem	n/a	0.3	n/a	--
Heart	68	2.2	94	--
Aorta	410	n/a	n/a	--
Spleen	n/a	14	239	--
Testes	72	n/a	176	--
Prostate	51	n/a	n/a	--
Kidney	22	3.4	158	--
Bladder	233	n/a	n/a	--
Stomach	116	n/a	n/a	--
Small intestine	19	n/a	n/a	--
Large intestine	25	n/a	n/a	--
Pancreas	68	n/a	n/a	--
Abdominal lymph nodes	123	n/a	n/a	--
Thyroid	328	n/a	n/a	--
Adrenal	99	3.6	1,008	--
Muscle	41	n/a	13	2.6%
Fat	29	n/a	4.5	--
Omentum				7.5%
Soft tissues				3.0%

**one picocurie is a quantity of any radioisotope sufficient to release 2.2 disintegrations per minute. Each disintegration releases ionizing radiation.*

***ref. #17*

n/a (not analyzed)

Table 2

Plutonium in body organs and cause of death for fifteen U.S. Transuranium Registry workers dying of natural causes, with less than 1% of the U.S. Department of Energy maximum permissible body burden of plutonium in their bodies (a)

case number	Age at death	cause of death	Plutonium body burden, picocuries (b)	urinalysis estimate of Pu in body	Organ with greates Pu concentration
02D00627	49	melanoma	background (c)	background	trachiobronchial lymph nodes
01JA0023	62	bronchogenic carcinoma	8 picocuries	minimal	pancreas
01AT0227	64	myocardial infarction	60 " "	minimal	trachiobronchial lymph nodes
01TM0002	70	mult./emphys./athero.	64 " "	400 picocuries	liver
02D00237	60	myocardial infarction	92 " "	0 " "	thyroid
02D00712	50	myocardial infarction	120 " "	0 " "	lungs
02D00449	60	myocardial infarction	120 " "	0 " "	trachiobronchial lymph nodes
02D00235	63	chronic lymph.leukemia	120 " "	0 " "	lungs
02D00711	50	myocardial infarction	160 " "	0 " "	trachiobronchial lymph nodes
02D00444	65	acute lymphoblastic leukemia	200 " "	0 " "	trachiobronchial lymph nodes
01AT0391	67	bronchogenic carcinoma	220 " "	minimal	muscle
02D00629	46	kidney, adenocarcinoma	240 " "	0 picocuries	trachiobronchial lymph nodes
02AE0006	55	bronchogenic carcinoma ("bronchus and lung")	240 " "	0 "	tracheobronchial lymph nodes
01TM0004	81	general debility, cor.insuf.	272 " "	1360 " "	liver
02D00710	56	brain tumor(astrocytoma)	360 " "	0 " "	lungs
mean age	59.9		152	—	

(a) From Norwood WD,Newton CE, Health Physics, 28:699(1975). One suicide, one accidental death deleted.
(b) Excluding plutonium in the lung, tracheobronchial lymph nodes and wounds. Amounts of plutonium are those found in organs after autopsy.
(c) several picocuries

Table 3

U.S. Transuranium Registry workers dying with less than 1% (400 picocuries) of the D.O.E. Maximum Permissible Body Burden of Plutonium: Cause of death and comparison with U.S. proportionate cancer mortality in males, all areas (a-c

	U.S. deaths, male age 60/100,000(a,b)		Transuranium Registry deaths (c)			
	no.	%	%	obs.	exp	o/e
ronchogenic carcinoma	145	7.00	20.0	3	1.05	2.9
Leukemia	10.7	0.52	13.3	2	0.08	25.0
rain tumor(astrocytoma)	11.1	0.54	6.7	1	0.08	12.5
alignant melanoma	4.5	0.22	6.7	1	0.03	33.3
idney adenocarcinoma	10.9	0.53	6.7	1	0.08	12.5
Total:	182	8.79	53.3	8	1.32	6.1
Other cancer	203	9.80	0	0	1.47	—
All cancer	385	18.59	53.3	8	2.79	2.9
all other causes	1686	81.41	46.7	7	12.21	0.6
Total causes	2071	100	100	15	15	1.0

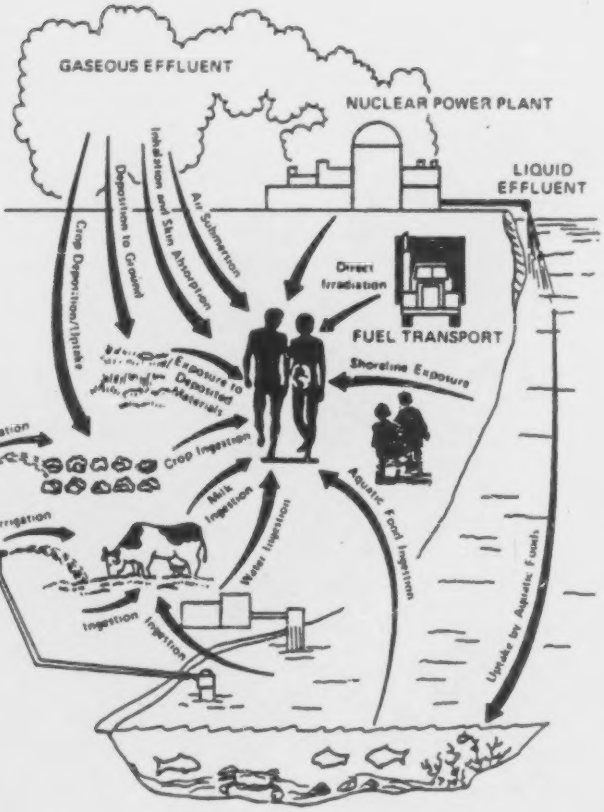
(a) N.C.I. Mon. no. 57, U.S. P.H.S.(1981) Cancer mortality data for all areas, males, age 55-60

(b) Vital Statistics of the United States, 1968, Vol. II A, U.S. Govt. Printing Office, Wash., D.C.(1972). Annual death rate for 60 year-old white males, less suicides and accidents (142/100,000)

(c) From Norwood WD, Newton CE; Health Physics, 28:699 (1975). One suicide, one accident excluded.

Figure 1

Pathways of Radiation to Man

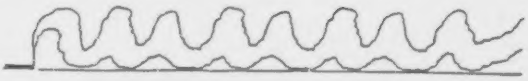

GASEOUS EFFLUENT
NUCLEAR POWER PLANT
LIQUID EFFLUENT
Crop Deposition/Uptake
Deposition to Ground
Inhalation and Skin Absorption
Air Submersion
Direct Irradiation
FUEL TRANSPORT
Exposure to Deposited Materials
Shoreline Exposure
Irrigation
Crop Ingestion
Milk Ingestion
Irrigation
Water Ingestion
Aquatic Food Ingestion
Ingestion
Ingestion
Uptake by Aquatic Foods

*This schematic figure is from NRC (Nureg-0139) and EPA documents. However, the children and the fetus have been added, since the NRC and the EPA consider only non-smoking adults. The children are about ten times more sensitive to radiation than the adults and the fetus about 20 times more sensitive. The children were taken from a photograph by W. Eugene Smith. (CJJ)

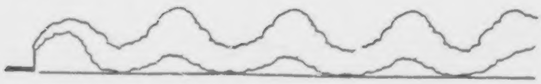
Figure 2

Plume behavior at various Pasquill stability classes

PASQUILL "A" STABILITY: LOOPING PLUME



PASQUILL "B" STABILITY:



PASQUILL "D" STABILITY: CONING PLUME

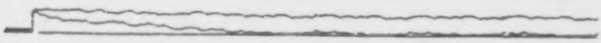
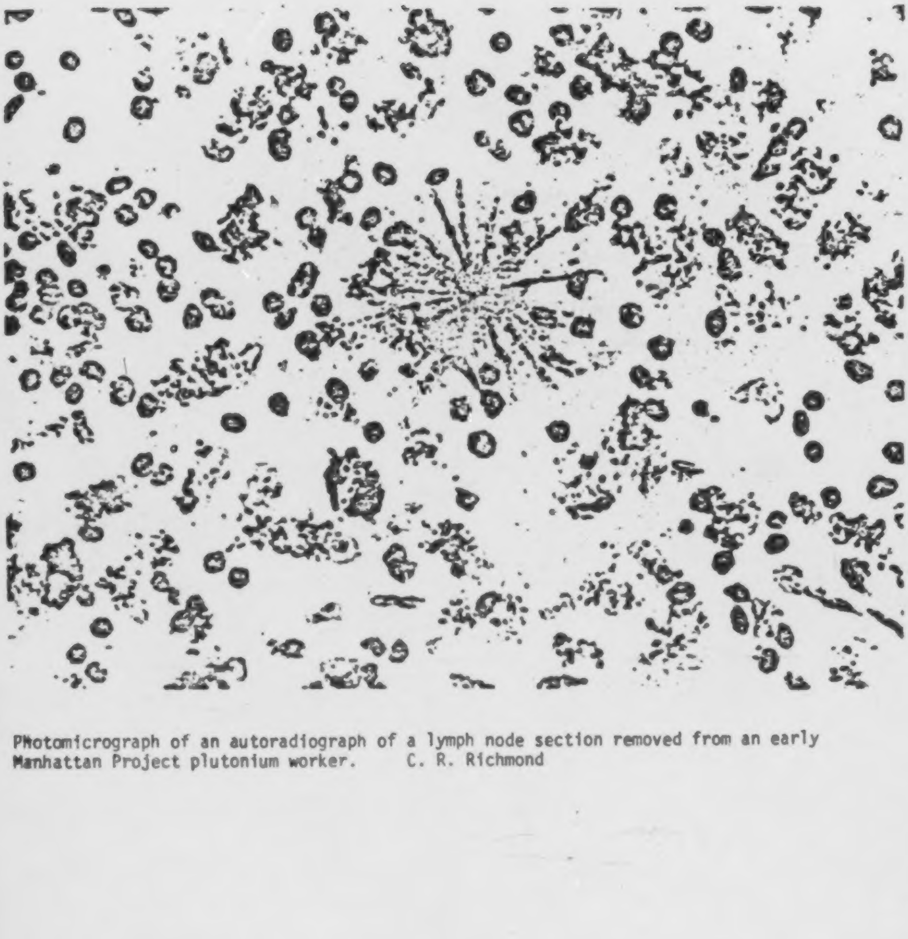
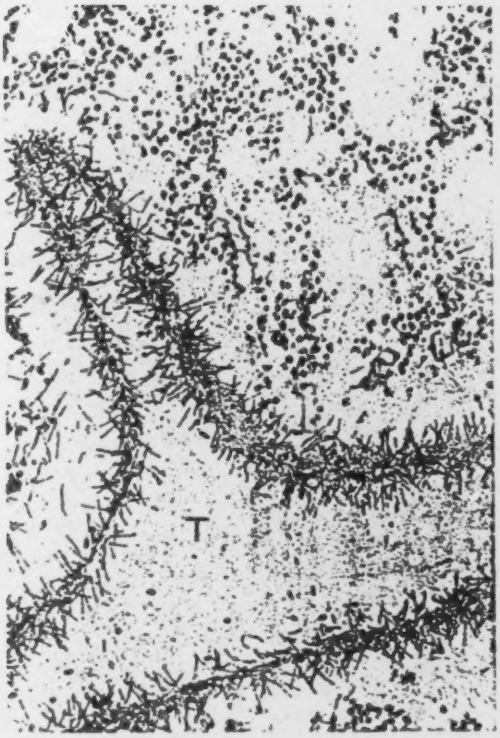


Figure 3



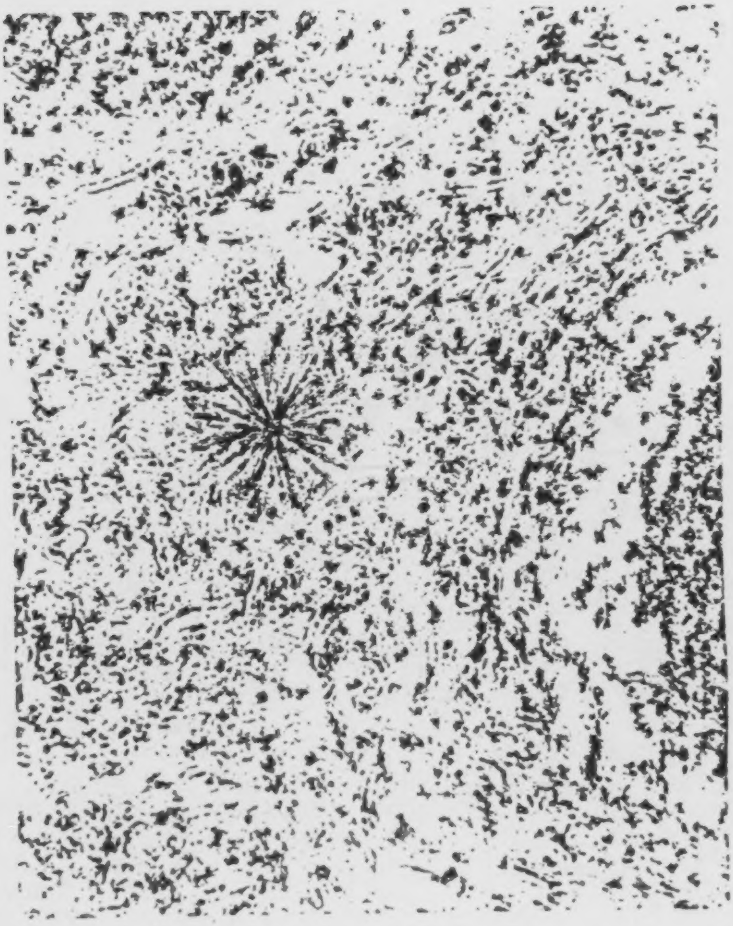
PHotomicrograph of an autoradiograph of a lymph node section removed from an early Manhattan Project plutonium worker. C. R. Richmond

Figure 4



Autoradiogram of bone trabecula (T) from a beagle showing the surface deposition pattern of plutonium. (Berdjis CC: Path of irradiation. Williams and Wilkins Co., Baltimore, 1971)

Figure 5



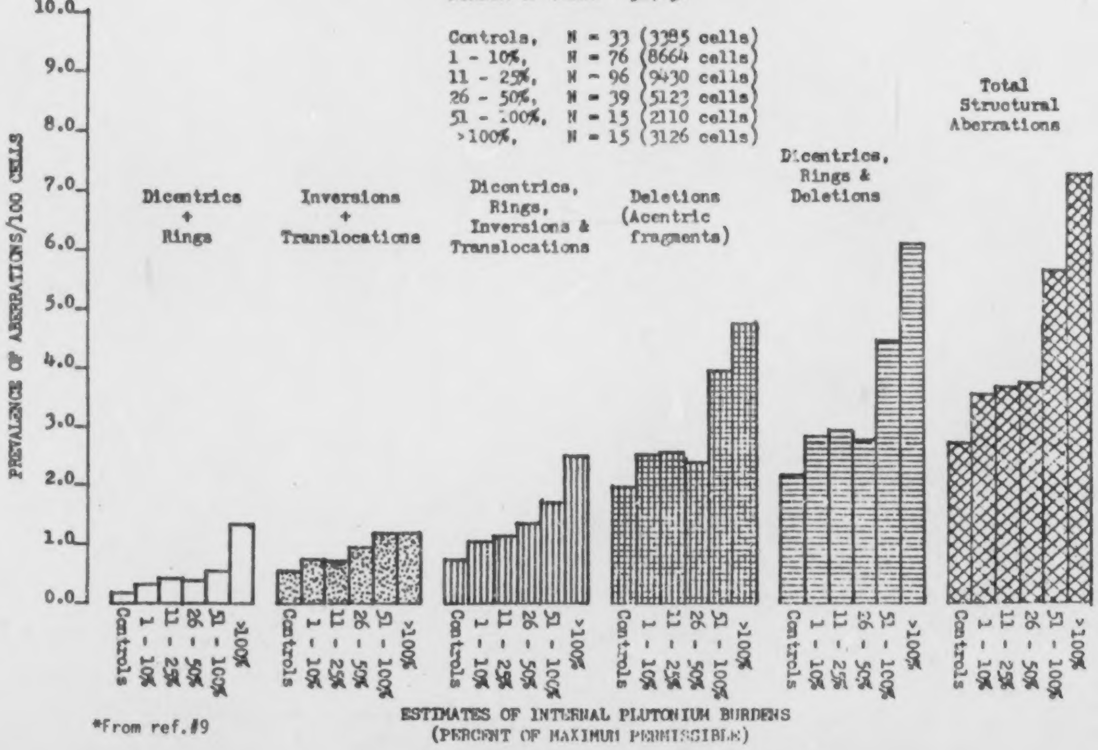
Autoradiograph of a plutonium particle in lung (from Brookhaven National Laboratory)

Figure 6

HISTOGRAMS OF THE PREVALENCE OF STRUCTURAL CHROMOSOME ABERRATIONS IN ROCKY FLATS CONTROLS AND PLUTONIUM WORKERS ARRANGED BY CHROMOSOME ABERRATION CATEGORIES*

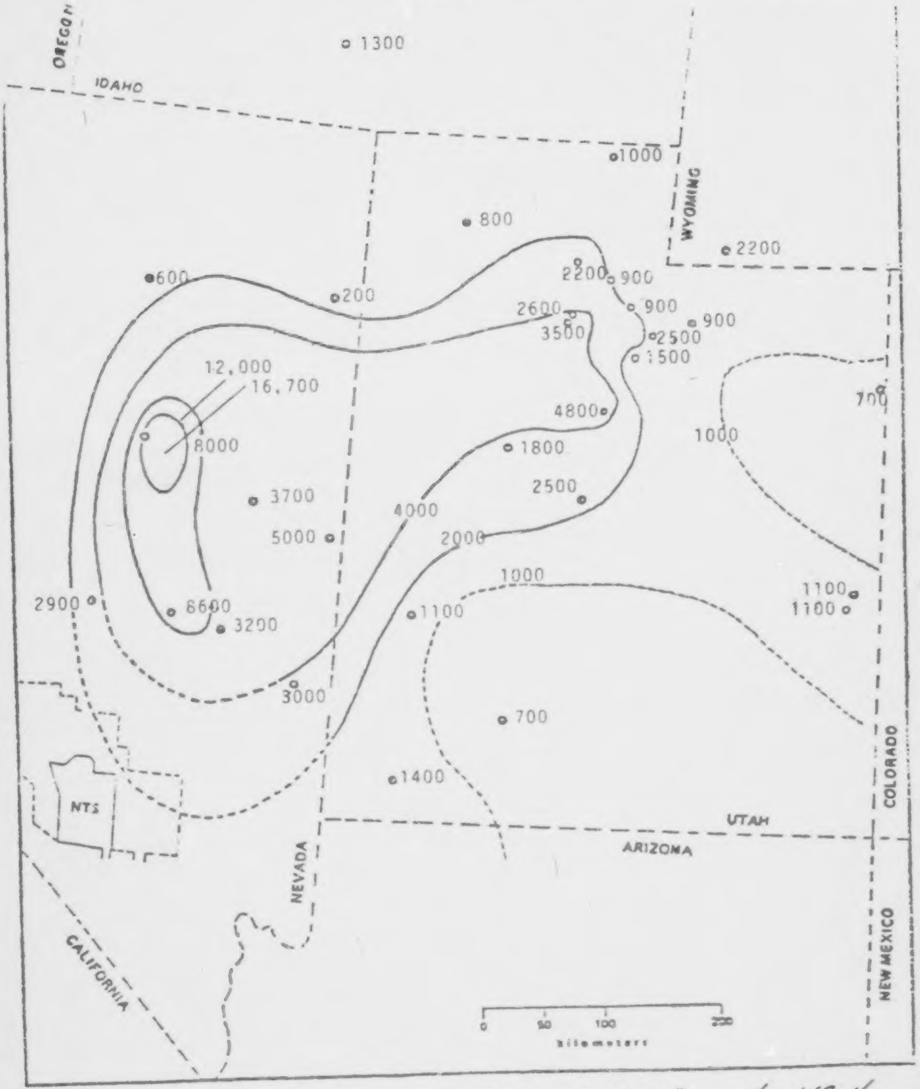
N = 274 MEN (PLUS 57 REPEATS)
NUMBER OF CELLS = 31,838

Controls,	N = 33	(3385 cells)
1 - 10%,	N = 76	(8664 cells)
11 - 25%,	N = 96	(9430 cells)
26 - 50%,	N = 39	(5123 cells)
51 - 100%,	N = 15	(2110 cells)
>100%,	N = 15	(3126 cells)



*From ref.#9

Figure 7


OREGON
IDAHO
WYOMING
NEVADA
UTAH
ARIZONA
COLORADO
NEW MEXICO
CALIFORNIA
NTS
1300
1000
800
2200
600
200
2200
900
2600
3500
900
900
2500
1500
12,000
16,700
700
4800
8000
1800
1000
3700
2500
4000
5000
2000
1000
1100
2900
6600
1100
1100
3200
3000
700
1400
0
50
100
200
kilometers

CUMULATIVE NTS DEPOSIT OF Pu-239,240*

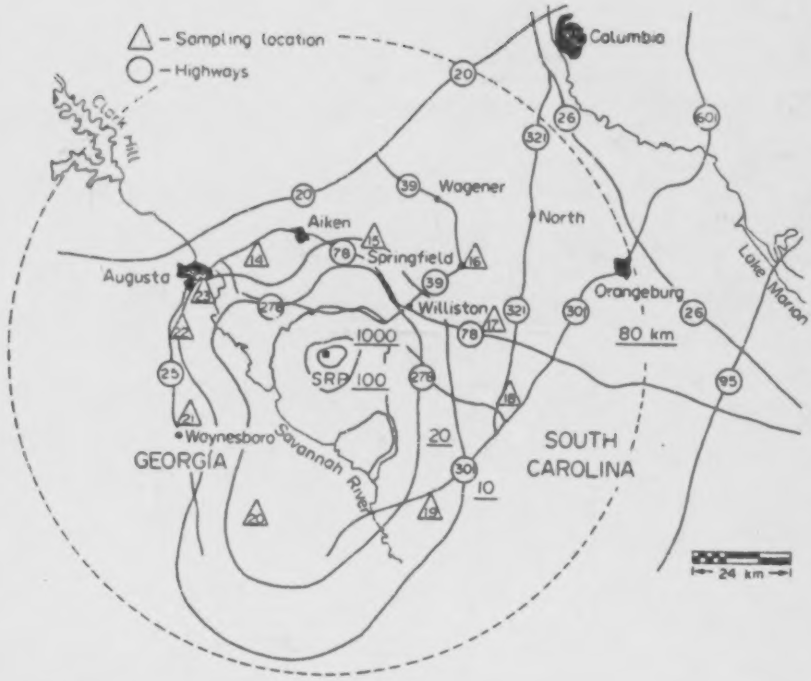
As of 1974

I - 71

Femtocuries of plutonium 239,240 from the Nevada Test Site per square centimeter
(a femtocurie of plutonium 239 yields 3.2 nuclear disintegrations daily)

*Background from worldwide fallout in North Carolina is 0.7 femtocuries/g or cm^2.

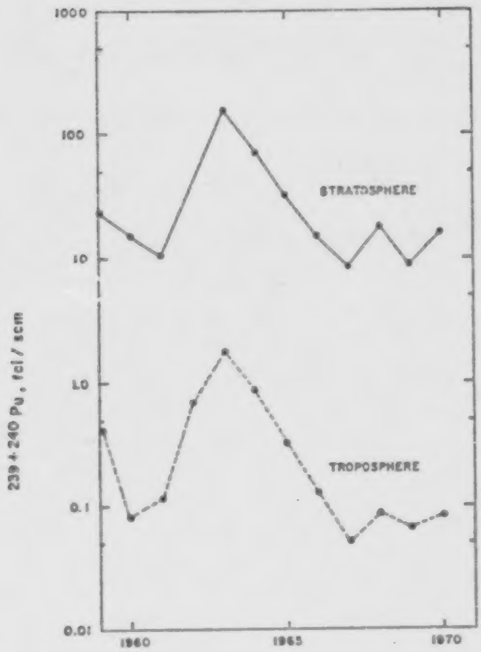
Figure 8


△ – Sampling location
○ – Highways
Clark Hill
Columbia
20
26
321
601
39
Wagener
North
Aiken
15
Springfield
16
78
14
Augusta
23
39
Williston
278
17
321
301
Orangeburg
26
80 km
22
1000
SRP
100
25
278
95
18
21
Waynesboro
Savannah River
20
SOUTH CAROLINA
GEORGIA
301
10
20
19
24 km
Lake Marion

Plutonium 238, 239 in fCi/g of resuspendable material (0-0.1 cm) or surface dust on soil around the Savannah River Plant. Ten fCi/g is about 14 times greater than background (0.7 fCi/g) by this method. Adapted from H.R. McLendon, et al. in Transuranium Nuclides in the Environment, pp. 347-363. The Int. Atomic Energy Agency, Vienna (1976) (Ref. #38).

Figure 9

Atmospheric Plutonium Levels *



Efurd D W, Merrill, Jr. G L, Phelps J T and Rosenlof K D: Measurements of americium and plutonium in the atmosphere (A report of the McClellan Control Laboratory, McClellan Air Force Base, CA 95652 (1977).

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD

FOR DR. CARL JOHNSON

1. Each of the three panelists that preceded you at the hearing on June 11 identified a number of key uncertainties in the "probability of causation" tables that have been prepared by the Ad Hoc Working Group. Aside from your views on the basic assumptions reflected in developing these tables, would you comment on the uncertainties that have been identified, and give us your view of the magnitude of these uncertainties?

2. Are those uncertainties of sufficient magnitude that, at this stage, we should consider further scientific analysis of this concept, before using these tables as a guide for compensating individual cancer claimants?

3. Have you undertaken an analysis of the "probability of causation" approach, and compared the results that you would reach if this approach were applied by the courts in any of the cases that you have been involved in, rather than the traditional tort approach presumably applied by the courts?

4. If one were to adopt all of the assumptions that you have advanced on the relationship between radiation exposure and cancer, and proceed from that basis to develop "probability of causation" tables, is this a methodology that, from a scientific standpoint, you would support as a basis for compensating individuals exposed to radiation who later develop cancer?

5. The Veterans Administration is currently considering whether it should employ the "probability of causation" methodology in the regulations that it is now developing under the "Veterans Dioxin and Radiation Exposure Compensation Standards Act". Do you support the use of this methodology by the Veterans Administration, in that context?

6. Do you, or the organizations that you represent, have any current plans to undertake a detailed scientific review of this effort--similar to what was done by the Mosteller Oversight Committee--to provide us with an independent assessment of the initiative? If so, would you be willing to share your results with us?

Phone 303/232-2328

42 Hillside Drive
Denver, Colorado 80215

Carl J. Johnson, M.D., M.P.H.
Research and Consultation
Epidemiology and Health Administration

August 27, 1985

Ronald Preston
United States Senate,
Committee on Labor and Human Resources
Washington, D.C. 20510

Re: Questions of Senator Allan K. Simpson

Dear Mr. Preston:

I have already returned under separate cover the corrected transcription of my oral testimony before the Committee. In this letter I respond to Senator Simpson's questions in the order in which they appear on his list.

1. The compensation panel lists 12 sources of uncertainty on pages 109-110: the dose to the individual, the source tables on cancer incidence, the influence of age at time of exposure, sex differences, cancer sites and cell types, minimal latent period, risk coefficients, dosimetry, epidemiological studies, dose-response functions, dose rate, time-response model and other risk factors. All of these sources of key uncertainty or error are very important and have not been adequately addressed in the report of the compensation panel. The uncertainties interact together to give additive and multiplicative effects on the final estimate of risks to any specific individual.

In addition, tha panel did not consider certain age groups that are more susceptible to radiation and excluded many classes of cancer which have been shown to be induced by radiation. I have discussed these sources of uncertainties or error, and also discussed others that must be considered in my oral and written testimony at the Committee hearing.

2. These uncertainties or sources of error are of sufficient magnitude separately (and especially when considered together) that these tables should not be used as a guide for compensating individual cancer claimants. Much further scientific analysis of this concept must be carried out by a new panel of experts who have had no present or prior association with the nuclear establishment. Such scientists should meet the same tests as that required of jurors impaneled to hear radiation compensation cases.

A much stronger science base is needed concerning the effects of radiation on health. The hundreds of millions of dollars which each year are funneled through the nuclear agencies to study the health effects of radiation must be redirected to those federal agencies whose primary mission is the protection and promotion of health of the public and of workers. I understand that Congressman Wirth and Senator Glenn have introduced such legislation. Much unbiased scientific research must be done in order to develop an adequate science base for such compensation tables.

3. The compensation panel relied on the BEIR 80 report which projects about seven cases of radiation-induced cancer for each case of radiation-induced leukemia in a population. In my analysis of the probability of causation approach I discovered that the panel would permit only three cases of radiation-induced cancer for each case of radiation-induced leukemia in a population. Even if the BEIR 80 report can be considered adequate and not outdated (as it is) the compensation panel has been very inconsistent.

In addition, the panel had excluded a number of cancer types which are known to be caused by radiation and excluded age groups which are more highly susceptible to radiation. In my role as consultant in radiation cases I have always relied on the BEIR 80 report, supplemented with research which has been done since 1979 (the last date of any publication cited in the BEIR 80 report). The BEIR 80 report, itself, is controversial. Where there has been controversy I have applied my own interpretation.

4. If all of the assumptions that I advanced on the relationship between radiation exposure and cancer were adopted, I believe this would result in stronger probability of causation tables that would be more accurate and just. However, I believe a much stronger science base is required, and this can be accomplished if the large research funds now going to nuclear agencies are diverted to those federal agencies whose primary mission is the protection of health of the public and workers, as I recommended in #2 above. If this is done, I would support such tables. I would still point to the need for considering each individual case separately.

5. I do not support the use of the methodology used by the current compensation panel for use by the Veterans Administration, to be applied to dioxin cases. The same concerns I have brought forward concerning the radiation compensation tables apply to compensation tables for veterans exposed to dioxin. If the points I advanced under points 1-4 are addressed, I think that I could support the use of this methodology with the same reservations.

6. I have, in fact, already undertaken a detailed scientific review of the report of the compensation panel which I presented in oral and written testimony to the Committee. This is an independent assessment of the initiative and is the sort of work for which I ordinarily charge $75.00 per hour as a consultant. In this case I donate this work in the public interest to the Committee in the hope that this will be helpful to persons who have been injured by radiation.

I thank you and Senator Hatch and the Senate Committee on Labor and Human Resources for the airfare to Washington to participate in the hearings on the radiation compensation tables.

Sincerely yours,

Carl J. Johnson

Carl J. Johnson, M.D.

The CHAIRMAN. I have run out of time. I have a number of questions for you, and I will submit those to you, and if you can respond in writing, we would appreciate it.

Also, Senator Simpson has questions for various panel members. So we will keep the record open until the end of this week for questions from members of the committee.

Yes, Mr. Alvarez.

Mr. ALVAREZ. May I make just one final comment about the National Academy of Sciences?

The CHAIRMAN. Yes.

Mr. ALVAREZ. A lot has been made about the objectivity of the National Academy. But even a prestigious institution like the National Academy is not immune from certain pressures.

In 1983, the National Academy, the National Research Council, specifically, released a report, timed it on the day that Congress designated "National Atomic Veterans Day." It was a survey of 20,000 GI's who were the first to enter Hiroshima and Nagasaki after the bombings. The basic claim made on the basis of this analysis is that there were no excess risks of multiple myeloma. This brought out some critiques by independent scientists, and the Office of Technology Assessment did review the NAS report. I just would like to make one quote from the OTA report:

> Except for assuming a population at risk of 20,000, at each step of the way the Council's methods contribute to an underestimation of the observed and an overestimation of the expected numbers of cases, making it less and less likely that an excess would be detected, even if it did exist.

I think that we need to sort of dispel certain folklores about institutions not being subjected to pressures. Everybody makes mistakes.

The CHAIRMAN. I think every institution is subjected to pressures. The question is with those pressures do they overcome the scientific and reasonable evaluations by those institutions. You know, next year, as I understand it, the Federal Government is going to spend approximately $58 billion on research and development. That is just in 1 year. It is pretty hard for a scientist to avoid Federal dollars no matter who he or she is, because they are all over the scientific place. Almost every scientist who is publishing today has had some help from the Federal Government.

The only thing I can say is do you really think——

Mr. ALVAREZ. Well, sir, I am not disputing——

The CHAIRMAN. Let me just finish—do you really think that Federal money so taints the scientific community that the public cannot get honest answers from the scientists? Do you really think that the Congress and the country should not trust the National Institutes of Health or the National Academy of Sciences, especially since we have provided for peer review, and we have kept the record open, and we are allowing cross-breeding of ideas, and certainly trying to get to the bottom of what various people think.

I mean, do you really think that the Nation's scientists are involved in some big giant conspiracy?

Mr. ALVAREZ. No, sir. I am not implying any impropriety of any individuals.

The CHAIRMAN. I hope not, because I do not believe that.

Mr. **Alvarez**. The point I am simply making is that we have to get beyond the issue of who do you trust. What we have to deal with are those mechanisms to ensure that abuses that have been documented in the past in terms of distortion of research and other things are not repeated. And an important aspect of this safeguarding process is to include people whose views are not necessarily considered mainstream.

I think that the issue here, again——

The **Chairman**. Well, I think you make a good point, that just because your views and those of Dr. Johnson and those of the other four people have been indicated as not being mainstream does not mean that they are irrelevant or invalid. And this committee does not take that position in any way, shape or form.

Mr. **Alvarez**. But one point, sir——

The **Chairman**. On the other hand, the other question that you have to ask is when you get much off the beaten track in mainstream science, do you get into a lot of theories that really are not important. For instance, we hear a lot about Nobel laureates on your side of this issue. Now, some of the Nobel laureates you have mentioned are not particularly educated in this particular field. On the other hand, Dr. Yallow, who has been called an extremist here, is a Nobel laureate. So you know, both sides can produce their Nobel laureates. The question is who knows what is going on here.

Mr. **Alvarez**. Well, again, it is not the issue of who knows what is going on. It has to do with making sure that you have safeguards available to ensure objective research, and the fact——

The **Chairman**. Well, how much more safeguards——

Mr. **Alvarez**. Well, I think an important safeguard would be the enactment of the Glenn-Wirth bill which would transfer the Radiation Health Effects Research Program to the Department of HHS. A major problem, I believe——

The **Chairman**. Who wants HHS to do it? Now, tell me that HHS is going to be less political than NIH or the National Academy of Sciences. I mean, my gosh, let's be reasonable.

Mr. **Alvarez**. Well, may I say, sir, that it would be less political than the Department of Energy. The Department of Health and Human Services has indeed——

The **Chairman**. Well, did they do these tables? Did the Department of Energy do these tables?

Mr. **Alvarez**. Well, at least one of the conflicts that HHS does not have is the mission to manufacture nuclear weapons as quickly and cheaply as possible.

Dr. **Johnson**. The mission is different.

Mr. **Alvarez**. The mission is different.

The **Chairman**. Well, OK. But you see why I am a little upset——

Mr. **Alvarez**. HHS is in the business of protecting public health.

The **Chairman**. Let me just say something here. You can see why I am just a little bit upset. You know, I have been working on this for almost my whole Senate career. It is a lonely, lonely battle. And I can tell you that I have worked my tail off to try and resolve this problem and to try and help the people that you want to help, too. And I think that the radioepidemiological tables victory was a victory. I think getting that done is a great thing.

Nobody suggests this is the absolute last answer—even the authors of the tables do not suggest that, and certainly, the National Academy of Sciences does not say that.

But for certain ideologues in the field to come in and suggest that all these people are in some giant conspiracy—which is really what you have to kind of deduce from some of the criticisms that have been made—that all of these people are in some giant conspiracy to make sure that there is a mainstream that keeps out the poor, sick, and afflicted is just garbage, as far as I am concerned.

Now, I think we have accomplished a lot here today, whether you do or not. I think we have had for the first time in our hearings scientists sit here and say that these tables can be used in a court of law. I think we have had all of them pretty well admit that there ought to be some compensation for people who have suffered as a result.

The question, then, that I am trying to find is how do we, from a legislative standpoint, resolve this problem so that justice occurs.

Now, I think the way we are going to do it is, if we are going to give $150 million to the Micronesians—and I think we should; I think that they have been injured and hurt—but I might add, everybody knew up front what was going to happen there—then, we ought to at least be able to put an equivalent amount of money in for those in our own country who are suffering.

And I know that the plaintiffs' lawyers do not want a mere $150 million; they want an open-ended governmental liability, if they can get it. And I cannot blame them for that. That is just not my job. My job is to try and get some reasonability into this situation and try and get justice for the people who have suffered so much out in Utah, Arizona, and Nevada, and I think we ought to take into consideration the veterans who have suffered and, I think, the uranium miners, because all of these things occurred to a degree because of the negligence of the Federal Government. When you and I are negligent, we have to pay the cost of that negligence. Why shouldn't the Federal Government do the same?

Now, all I am saying is that I think there has been a lot of criticism thrown here and there and round about, and it is easy to criticize, and it is easy to find fault. But we have come a long way from where we were when we first started on this thing, and I think this hearing has been very helpful today.

Let me just say this. We appreciate having your testimony. Your point is well taken, because you are not in the mainstream does not mean you are not right. I am the first to acknowledge that. And because these other doctors are not in the mainstream of science, it is no assurance that they are not right, either. But I might add, it is no assurance that you or they are right, either. And all I can say is if you cannot rely on the National Institutes of Health, if you cannot rely on the National Academy of Sciences, if you cannot rely on peer review, if you cannot rely on the mainstream scientists, then we are all in pretty rough shape, unless you can bring on actual definitive evidence.

Now, I do not think anybody here says that these tables are the absolute last word that ever is going to be said in the area of the effects of nuclear radiation on human beings. They are just not; nobody said that. But they are a start. And nobody is saying that we are going to judge all these cases based on what these tables say. The tables themselves appear to me to provide—would provide compensation or a means of proving causality in a limited number of cases. Who is going to define that number? Well, I suspect we have got to do it here in the Congress if it is ever going to be resolved. Now, I would prefer a lot more help than all the criticisms that we have had because our goals, I think, probably are the same, except that mine may be that I do not want to compensate people who do not deserve to be compensated. I do not want to saddle the taxpayers with untold hundreds of millions of dollars that they do not deserve to be saddled with. But I do want justice, and I do want it done, and I do want it done now, not 9 more years from now. And we are never going to get there if we do not kind of unify here and start getting behind a few people who stand up and do what really has to be done here. And there are darn few right now.

I remember back in 1982, this thing was really moving along through the Labor Committee, through this very committee. I had virtually every member on this committee, except one or two, who were for this bill. But it just happened to be that that was my election year. And when we got to the Judiciary Committee, all of a sudden, I had no help from Utah, I had no help from the out-of-mainstream scientists. I had no help from the mainstream scientists. As a matter of fact, I had no help from members of this committee on the Democratic side, who all of a sudden thought that maybe Orrin Hatch could be defeated, and if he passed this through, maybe that would stop him from being defeated.

Well, as it was, I lucked out and got reelected anyway. But it was a pretty pitiful thing to put whether or not I could be reelected or not—and I might add, our Utah Democrats were not actually excited about getting this through at that time for that reason, too—but it was a pretty pitiful thing to put whether or not Orrin Hatch could be reelected against whether or not we do justice for people here in this instance who have been actually injured as a result of the negligence of the Federal Government.

Mr. ALVAREZ. I would like to say that our organization worked a great deal of time and effort trying to support your legislation.

The CHAIRMAN. Excuse me?

Mr. ALVAREZ. Our organization spent a great deal of time and effort——

The CHAIRMAN. I am not just talking to you. I kind of like a number of the things that you have said. I am talking to Dr. Johnson and everybody else, who have done nothing but criticize, instead of get behind and help. I think we are going to have to help this time, because I see less support now than I had generated in 1982.

Mr. ALVAREZ. Well, I think it also depends on how you define "mainstream," because there is a mainstream of people in this country who work in the Department of Energy plants, who live near the Department of Energy facilities, who believe that they cannot trust the information that is being presented to them by the research establishment, funded and supervised by the very same people responsible for exposing them. That is a fundamental problem. And all we are merely saying is our organization is not opposed to the concept of risk tables per se. What we are concerned about is that the risk tables can be done in such a way with the priority being to limit the losses of the Department or the Federal Government, as opposed to providing compensation.

The CHAIRMAN. I think everybody has shared your concern there. I have shared that myself. But you know, to just presume that all these great scientists, who cut across the spectrum, really, on the panels, are just doing it to protect the Federal Government is just, I think, the wrong presumption.

I think we have got to—and all of them have said these tables are the beginning, they are not the end, and that we need to continue to study, and we need to continue to accumulate data, and so forth.

Well, we could debate this for a long time. I just want to personally thank both of you for appearing. I believe your testimony is very important to this committee, and you both have made some very interesting and, I think, important comments here. But I also want to set the record straight that I think that there are a number of people who are sincere who may not share your viewpoint and who are very learned in this field, as well.

Be that as it may, all I can do is do the best I can, because I am certainly no scientist, and I cannot make these determinations myself, so all I can do is provide that we have the means whereby we get there.

Why, one of the major editorials in Utah in our major newspaper out there claimed that I appointed the members of the panels. That is how far it goes. Now, you know, I hate to teach civics lessons to my own newspapers out there, but that gets a little old after a while. My goal was to get the best people we possibly could and let the scientific community do that, which I think they tried to do, and I think in reality, they did.

Your goal—and I think it is a viable, reasonable, good goal—is to point out the defects in this report, or to point out what you consider to be the improvements that should be made as we continue down this path of trying to come to an ultimate result that will help us all, that will help resolve this and, above all, get justice. And I think to that extent, this hearing has been a very, very valid hearing. I look forward to tomorrow's hearing when we will get into a lot of policy considerations. I suspect that is going to be more volatile than this particular hearing has been.

Dr. JOHNSON. Senator Hatch.

The CHAIRMAN. Yes, Dr. Johnson.

Dr. JOHNSON. I would like to see a totally new panel appointed to do this process, and they can make use of the work that has been done.

The CHAIRMAN. Well, who would you suggest appoint the panel?

Dr. JOHNSON. The new panel members, I think, should be screened for objectivity and their past background, because it is a matter that is rather sensitive. And why not expect a scientist to meet the same test that you would for a panel of jurists that hear a radiation compensation case?

The CHAIRMAN. Well, you cannot pick them on the basis of a jury selection. My gosh——

Dr. JOHNSON. Along with their science background.

The CHAIRMAN. I like your idea, but you cannot do that. How do you get anybody who is less committed one way or the other than Dr. Mosteller? I mean, really, in all honesty, he took no sides in this matter, and how do you get somebody better?

Dr. JOHNSON. These people, Senator, I have seen testify on behalf of corporations and nuclear agencies against plaintiffs.

The CHAIRMAN. And you have seen some testify against.

Dr. JOHNSON. Yes. And some have worked for the Atomic Energy Commission, which is now represented by the DOE.

The CHAIRMAN. Well, if you look at the influence Dr. Yalow has had on this report, she did not have a great deal of influence on it, in my opinion.

Dr. JOHNSON. It also says her area of expertise is not in the area of radiation effects. She is not an expert in radiation effects. I think you must have experts in radiation effects.

The CHAIRMAN. But my point is that I do not think that her particular position was very much adopted by those who came up with these tables.

Mr. ALVAREZ. Well, prior to her joining the committee, the committee was moving in a much more, I believe, conservative direction relative to the risk coefficient. And when she joined, I think a compromise was basically made, that being in exchange for relative risk model, the bulk of the cancers would be subjected to the linear-quadratic model—which we can quibble about. But I am not saying that these researchers are motivated to protect the Government. But what is at stake here—and every scientist has this—is a motivation based on a career investment that your study is right and the others are wrong, and——

The CHAIRMAN. Well, I hope you are wrong, because if that is so, then we cannot rely on any scientific conclusion——

Mr. ALVAREZ. No, no. I think you have to rely on these individuals, sir, but you have to include the other individuals who say "My study is right and not wrong," and you work out the differences.

The CHAIRMAN. That is right. The National Academy, of course, wanted that as well, so that is where we are. So you know, you could debate this forever. All I can say is that I hope we can resolve this problem one way or the other, and I hope that we can get the best that you have to offer, coupled with the best that the tables have to offer, and ultimately, reach a point where we can have jome justice in these areas.

But what I suspect, and I suspect it is true, is that we have had a number of people who are dedicated to one side or the other, but in particular, those dedicated against the nuclear power industry in this country, who have been using my people in Utah as a basic focal point to make their cause against nuclear power known. And I do not think that should be part of this. But nevertheless, I think you have to conclude that it is, when you look at some of the statements that are made.

Well, with that, we will recess until tomorrow, when we will begin these hearings and finish the second day of hearings.

[Whereupon, at 1:15 p.m., the committee was recessed, to reconvene Wednesday, June 12, 1985, at 9:30 a.m.]

RADIOEPIDEMIOLOGICAL TABLES

WEDNESDAY, JUNE 12, 1985

U.S. SENATE, COMMITTEE ON LABOR AND HUMAN RESOURCES, AND THE SUBCOMMITTEE ON NUCLEAR REGULATION OF THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,

Washington, DC.

The committees resumed in joint hearing, pursuant to notice, at 9:40 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin Hatch (chairman of the Committee on Labor and Human Resources) presiding, with Senator Alan K. Simpson, chairman, Subcommittee on Nuclear Regulation.

Present: Senators Hatch, Simpson, Grassley, and Kerry.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. This morning, we meet for the second hearing on the NIH radioepidemiological report and the issue of "causality" in radiation/cancer cases.

Yesterday's hearing was devoted to the science in the NIH report. Today's hearing will be devoted to the report's policy implications and potential uses.

It was clear from yesterday's testimony that the radioepidemiological tables are not a panacea. Everyone agreed that the science is insufficient for certainty in assessing the causal link between a radiation dose and a subsequent cancer.

Still, the three scientific committees which developed and reviewed the report agreed that it does represent the best available science and the best available method for evaluating radiogenic cancer claims. The NIH report represents a refinement of the scientific computations that expert witnesses have been making all along, albeit abstrusely and idiosyncratically. There is nothing new to the probabilistic evidence presented in the NIH report. The courts have been using it for years. The NIH report simply reveals this evidence for what it is.

Representatives from the NIH committee clearly felt that the NIH report should serve as a reference in courtroom proceedings. Neither they nor anyone else have claimed that the tables should be taken as face value as the last word on the question of causality in any given case. The NIH committee openly acknowledged that there are uncertainties and recommended that the tables be viewed within the context of the report's description of these uncertainties. However, a 2-year effort by an eminent scientific panel is almost certainly more credible than an ad hoc effort by a randomly selected expert witness.

The tribunals that judge radiation/cancer cases must contend with a complex and controversial science. They have not been doing well with this task and can use some help. And I am not certain what the ultimate solution should be. But at the very least, the courts' and the workers' compensation boards should have some guide to evaluate the credibility of the expertise and the testimonies of expert witnesses.

My hope is that the NIH report will provide both ballast and perspective. The purpose of this hearing is to discuss whether this is a realistic expectation and to consider how the tables report might be used for this purpose.

There can be no justice unless liability is predictable. This predictability is impossible without some consensus concerning the basis for the liability. Public acceptance of nuclear technologies is jeopardized by anything less than a reliance on the best available assessments of the relationship between radiation and cancer. We all have a large stake in ferretting out just what the scientific community knows about radiation/cancer causality and making this information comprehensible to the courts and ultimately to the public.

So this is a very important hearing, and we are looking forward to proceeding with it here today. First, however, we will insert the opening statement of Senator Kerry in the record at this point.

[Opening statement of Senator Kerry follows:]

OPENING STATEMENT OF SENATOR KERRY

Senator KERRY. I feel great compassion for those victims of radiation exposure who have suffered the agony and anguish of cancer. I feel compassion because of the pain they have endured and because they have been afflicted by a disease for which scientific uncertainty frustrates their attempt to obtain fair and just compensation for their suffering. As we know, scientific uncertainty arises in two situations: In cases where information is insufficient, and in cases where there are gaps in scientific theory. In these situations, it is necessary to make assumptions to bring the uncertainties, and these assumptions can vary in their degree of conservatism. The National Academy of Sciences explained this point very well in its critique of the risk assessment process for chemical carcinogens.

Because of the uncertainties inherent in the issue of compensating radiation victims, I believe we must be very thorough and careful in evaluating any decision framework which may be used in sorting out claims. Any such framework should clearly identify the uncertainties involved, the options available for bridging those uncertainties, and the consequences of exercising those options. I believe we need to focus on whether the NIH radiation tables serve as a framework which meets these criteria—whether they adequately describe the decision points where inferences are needed in the face of uncertainty, and the degree of conservatism associated with those possible inferences.

These hearings represent a positive first step in evaluating the NIH radiation tables. Given the complexity and importance of this issue, I believe it is appropriate for this evaluation to continue among the general scientific community and other interested parties.

The CHAIRMAN. We are pleased to welcome as our first witness Deputy Assistant Attorney General Robert Willmore to begin today's hearing. The Department of Justice is clearly the lead Federal agency in combating the radiogenic cancer claims that are made against the Federal Government. There was no other way to put it, since opposition seems to be the essence of the Department's policy in this matter.

I understand that departmental policy also prohibits Mr. Willmore from any specific discussion of ongoing cases. I will try to honor this injunction, although there is one ongoing case n particular that I would very much like to discuss.

Most of my concerns can be met by discussion of the law in general, on hypothetical terms.

So, Mr. Willmore, we are happy to welcome you to the committee. We look forward to taking your testimony and having some time to ask you some questions afterwards. So, please proceed with your testimony.

STATEMENT OF ROBERT L. WILLMORE, DEPUTY ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, U. S. DEPARTMENT OF JUSTICE

Mr. WILLMORE. Thank you, Mr. Chairman, and good morning.

I am pleased to be here today to present the views of the Department of Justice on the impact of the report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables on claims filed by persons seeking compensation for injuries allegedly caused by exposure to low levels of ionizing radiation.

The United States presently is a defendant in a substantial number of suits in which the plaintiffs assert that they are entitled to damages for exposure to low levels of ionizing radiation. These suits, which are brought under the Federal Tort Claims Act, include over 4,000 individual plaintiffs. The single largest portion of these lawsuits arise from the atmospheric atomic weapons testing program conducted in the fifties and early sixties, commonly known as the downwind radiation cases. While the radiation exposure suits present numerous and often very different legal and factual issues, our experience, gained through the litigation process, gives us the benefit of direct knowledge of the factors which we believe are likely to bear on consideration of the report for use in any context involving claims of personal injury.

The touchstone for credible claims resolution must be individual consideration of each and every factor bearing on the plaintiff's condition. Age, weight, family history, occupational environment, exposure to sunlight, smoking, diet, exposure to known carcinogens, and many other aspects of a person's life may bear on causation of cancer, to the extent that causation is ascertainable. The judicial process requires, reasonably enough, that the characteristics of the plaintiff before the court, rather than a hypothetical or average person be examined, in order to reach a considered, fair judgment as to causation.

This approach to causation, which applies to all of tort law, is equally applicable to claims alleging injuries due to exposure to low levels of ionizing radiation. As Judge Patrick Kelly recently noted in *Johnston* v. *United States*, a case involving allegations of cancers from occupational exposure to low-level radiation:

> We can see that in matters of determining the cancer risk from low occupational doses of radiation, scientists do not deal with what exists in fact, and can be measured or experimentally proven. Rather, they deal with theory, hypothesis and assumption. While such an approach is a valid way to set general safety standards, it cannot be used to establish legal cause through mathematical calculation.

Indeed, the ad hoc working group notes this very point in its report, when it observes:

> PC calculations based on SEER values for baseline cancer incidence require the assumption that the individual in whom cancer was diagnosed following a documented radiation exposure would have been, in the absence of that exposure, "typical" of the U.S. population for his or her age and sex with respect to cancer risk. But the subject may have had an atypical history of exposure or nonexposure to known carcinogens or may have experienced other life events associated with a higher or lower cancer risk than average. Or the subject may be a member, perhaps even a "typical" member, of an ethnic, religious, or other population subgroup, known to have cancer rates higher or lower than the U.S. population as a whole."

Later, in the same section of the report, the working group concludes with the following statement:

> Clearly, the problem of calculating PC values in the presence of differences in total cancer incidence because of exposure to other carcinogenic agents, personal history with respect to factors related to cancer risk, or membership in a particular population subgroup is fraught with uncertainty.

Thus, such radioepidemiological tables, while perhaps providing valuable insight on the probability of causation on a hypothetical typical person with cancer, will likely have only limited value in the context of the much more extensive and detailed information available on a particular plaintiff alleging injury from a specific exposure. And, as noted, it is our firm belief that any system of compensation, and particularly the tort system, must rely on determinations of causation based on each individual's unique and specific case if it is to be viewed as fair, reasonable and credible.

In emphasizing the inherent limitations of causation, I do not wish to overlook the fact that there are uncertainties in the probabilities assigned in the working group's report—even assuming the typical individual could be found, which would limit their use in determining causation. You have already heard extensive testimony and will be hearing additional testimony on the many assumptions and uncertainties underlying this report, and I therefore will not detail those uncertainties and assumptions here.

I would note, however, the working group's own statement that "The tables cannot now provide precise measures of the probability that certain cancers have resulted in previous exposures to known doses of ionizing radiation."

For this reason, the working group cautioned that "The tables can be regarded as no more than a guide to causation."

In sum, we believe that while the report is a valuable scientific document which merits careful attention, it is not appropriately utilized as a determinative factor in resolving any individual's claim that exposure to low-level ionizing radiation caused his or her cancer.

This concludes my prepared statement, and I would be happy to answer your questions.

The CHAIRMAN. Well, thank you, Mr. Willmore.

Mr. Willmore, does the Department of Justice hold that it is its mission to win cases brought against the Federal Government by every legal means available, including every legal technicality, whatsoever truth or moral merit there may be to some of these plaintiffs' complaints?

Mr. WILLMORE. Senator, we assert the legal defenses available to the United States of America under the Federal Tort Claims Act, including defenses such as the discretionary function defense, the statute of limitations and other defenses. I suppose they could be——

The CHAIRMAN. And sovereign immunity, I take it, as well.

Mr. WILLMORE. The Federal Tort Claims Act is a waiver of sovereign immunity. So we do not go into court and assert sovereign immunity. What we do is we go into court and state that our liability is defined by the Federal Tort Claims Act which, of course, Congress enacted. The Federal Tort Claims Act establishes certain defenses which we will assert if applicable in any tort lawsuit brought under the Federal Tort Claims Act. The Federal Tort Claims Act arises from the waiver of sovereign immunity.

The CHAIRMAN. Well, under tort law, the question of causality is, of course, only one of the issues that has to be addressed in making a case. In fact, the question of causality may be moot if certain other preliminary conditions are met pertaining to such things as duty or negligence. Regarding the Federal Government as a defendant, prospective plaintiffs, as you know, face a special hurdle. They consider the Government only under the terms, as you have stated it, of the Federal Tort Claims Act, which entails something called discretionary exceptions.

Am I correct on that so far?

Mr. WILLMORE. Yes. It contains what is called the discretionary function defense.

The CHAIRMAN. Now, essentially, the discretionary exception or discretionary function defense prohibits an award of damages when the alleged wrong was a direct and inevitable result of Federal policy. And this provision is relative to today's discussion because the discretionary exception, as it has been variously interpreted, directly affects the significance of the causality question.

If this exception is interpreted so broadly that virtually anything that a Federal employee decides to do is policy, then what we are considering here today is of little relevance to the Federal Government.

Now, your office need not be concerned with knowing when radiation caused a cancer. Therefore, we turn to causality. And I would like to probe the Justice Department's view of the discretionary exception by way of a hypothetical example, if I can.

Mr. WILLMORE. All right.

The CHAIRMAN. Suppose that for reasons of national security, a Federal official decides that a poison gas factory has to be built. Another official decides that it must be built in community "x." Another official decides that the community residents should not be told the true danger of the plant, since this might lead to public protest that might jeopardize the program. Another official decides to use a public relations campaign to convince the community through films and lectures that there is no danger from the plant. Another official decides a rigorous program of monitoring gas leaks might upset the community, and so he decides to send only a few jeeps around with air samplers made of modified Electrolux vacuum cleaners. And finally, the last official decides not to keep adequate records of the doses of gas from the plant, since the questions and actions needed for the data would also upset the community.

Twenty years later, the community residents bring suit against the Federal Government. They allege that the Government was negligent in failing to warn them of the dangers of the plant and of failing to monitor them adequately. They charged that the gas leaks from the plant caused their heart disease, and let us presume for the sake of argument that this last charge is true—the gas leaks did, in fact, cause their heart disease.

Now, Mr. Willmore, in the view of the Justice Department, would the discretionary exception bar the claims of these community residents, and is it the Department's view that the discretionary exception bars claims even when the Government was clearly negligent and even when the Government's actions did harm or kill American citizens? Is this always so, and if so, do you think that this is fair?

Mr. Willmore. Senator, first of all, let me emphasize that the discretionary function defense, of course, is not a defense to every act by a Federal official. The courts have worked out a distinction between discretionary decisions, which are essentially policy decisions, and operational decisions—nonpolicy decisions. And there is, admittedly, a great deal of disagreement between courts as to where that line is. The Supreme Court has dealt with this issue on a number of occasions, most recently last year in the *Verig Airlines* case.

Much of what you describe in your hypothetical I think we would argue falls within the discretionary function defense. I do not know necessarily if every court would agree with us on that.

In answer to your last question, if the discretionary function defense applies, it is accurate that the United States would not be found liable under the Federal Tort Claims Act, even if there were acts of negligence. The reason for that—which is something that Congress worked out many decades ago—is that without the discretionary function defense, the system of health and safety regulation that we have in our country would be unworkable. It would be unworkable because every time the United States makes a policy decision involving health and safety—and frequently, those policy decisions involve whether to regulate or to inspect or to test something—frequently those policy decisions will result in somebody being injured. Often, the Government decides between what groups are going to be injured.

If the United States could be sued successfully under the Federal Tort Claims Act every time that kind of a policy decision is made, then it would become prohibitively expensive for the United States to do the kind of health and safety regulation that it does today. As I have stated on many occasions, the system of health and safety regulation that we have today would be impossible without the discretionary function defense.

The CHAIRMAN. But is there no discretion with the discretionary function defense for the Government to use its discretion and say that this would be clearly unjust in this type of a situation, where you have facts like these, where the Government clearly is at fault, clearly was negligent, clearly failed to warn, clearly failed to do the things that should have been done; is there no right to use discretion under those circumstances and resolve this problem?

Mr. WILLMORE. Well, that is where Congress comes in, Senator. It used to be——

The CHAIRMAN. You are saying that the Justice Department does not have a right to use discretion to determine that maybe in this particular instance there was enough to justify a discretionary exception to the discretionary function defense?

Mr. WILLMORE. I am not familiar with the discretionary exception to the discretionary function defense. However, we do, of course, have the authority to compromise and settle claims. And we have on occasion settled claims where we might have been able to successfully assert the discretionary function defense, but where we decided that it was a close question, and that rather than go to trial—and who knows how the court might decide the case—we obtained a good compromise settlement offer which we accepted.

On the other hand, if we think the discretionary function defense on its face applies, then yes, I think it is our responsibility—because that is the law that the Congress enacted—to assert the defense in a tort claim against the United States under the Federal Tort Claims Act.

The CHAIRMAN. Well, then, should there be special legislative remedies? Since you feel that as the attorneys for the Federal Government you must assert whatever defenses the Government has, you are saying the only answer, then, would be for Congress to enact statutory remedial legislation to resolve this type of a problem, which clearly is on its face a very bad situation and clearly one where the Government probably has liability—would have liability if it were an ordinary citizen?

Mr. WILLMORE. Well, let me answer both your questions. First of all, your last question—I do not agree that the United States would be found liable if it were an ordinary citizen. But clearly——

The CHAIRMAN. Under that hypothetical? I would sure like to be plaintiff's lawyer in that case.

Mr. WILLMORE. Not necessarily under that hypothetical. I would have to study that hypothetical more carefully, Senator. When you said "that case," I assumed you meant the downwind radiation types of cases.

The CHAIRMAN. Well, I used the hypothetical with particularity, because there are a lot of similarities between that and the downwind cases.

Mr. WILLMORE. Right. I understood that.

Well, I think that brings us to the issue of causation, and under causation, I do not think the United States would be found liable, and I appreciate——

The CHAIRMAN. Now, you are saying under causation as the method of proof requires today.

Mr. **Willmore.** Under standards of causation as they have developed over centuries under tort law, under common law tort law, the activities of the United States were not the proximate cause of the cancers—usually cancers—that many of these plaintiffs are asserting in these lawsuits.

The **Chairman.** Well, staff brings up a good point. What if the people cannot make the case because of the negligent failure of the Government to warn or to protect or to do whatever Government functions are basically and reasonably required?

Mr. **Willmore.** That is, in fact, something a court under well-established doctrines can take into consideration.

The **Chairman.** But you are saying that even though—or let me see if you are saying that—even though you can prove the negligence of the Government—let us assume that we can under the hypothetical—we can prove the negligence of the Government, the case may still fall because nobody can prove exactly, because the data was not kept, and the information was not brought together, even though the Government had an obligation to do so, that the data was not kept, the information was not there, and that nobody could prove that this particular person's heart disease, or in the case of the radiation cases, this particular person's cancer, actually came from the radioactive tests or, in the hypothetical, from the gas emissions.

Mr. **Willmore.** I think if one party has a duty to keep certain information, and another party cannot prove its case, and that duty was tehreby clearly and negligently violated, there are applicable judicial doctrines under State law. The Federal Tort Claims Act adopts State law, which can be used by the courts to deal with such a situation. It is not an unusual situation. Nor is it something limited to this particular area. Such doctrines exist. The result that would be achieved through application of those doctrines may vary from State to State and the tort jurisprudence that is developed, but they exist and they would apply to a claim that is adjudicated under the Federal Tort Claims Act.

The **Chairman.** Well, couldn't the citizens in the fifties and sixties have monitored radiation affectations or radiation emissions?

Mr. **Willmore.** Could they have monitored?

The **Chairman.** Yes, in the fifties and sixties.

Mr. **Willmore.** I do not know the answer to that question——

The **Chairman.** Well, I do. The answer is they could not have. The only one that could have under the circumstances would have been the Government, and the Government did not. Now the Government comes in and says because there are no standards, because there are no tests, because there is no data that we should have collected to begin with, even though we failed to warn, and even though we wanted to until the winds were blowing over the downwind communities so that they would be, with their sparse populations, the ones to get hit; we can and must and should avoid all liability for it.

Mr. **Willmore.** No, Senator, I do not agree that that is the Government's position. These trials involve extensive attempts at dose reconstruction. And of course, there is disagreement——

The **Chairman.** Yes, after the fact, many years after the fact.

Mr. WILLMORE. Sure, after the fact, but that is true of a lot of toxic torts cases, Senator, not just radiation cases.

The CHAIRMAN. Sure. But we are not talking about toxic torts where the Government may or may not have had any responsibility. We are talking about a case where the Federal Government deliberately set those shots, deliberately set them in a way that the fallout would fall over downwind, sparsely settled communities, rather than to the West, deliberately failed to warn, deliberately did no data collection. You could go on and on. But you are talking about some pretty serious allegations under the Federal Government under these circumstances. And if there is ever a case for judicial activism on the bench—and I am generally a decrier of judicial activism—it seems to me that you are setting the Government up for a tremendous dose of judicial activism in the future, just to right what really are very apparent wrongs.

Mr. WILLMORE. I agree with you that findings of liability under these facts would indicate judicial activism.

The CHAIRMAN. The findings in the *Allen* case, you are saying?

Mr. WILLMORE. No; I would rather not discuss the specifics of the *Allen* case.

The CHAIRMAN. That was the implication.

Mr. WILLMORE. But Senator, dose reconstruction, and not just for radiation—for it can involve dose reconstruction for agent orange; it can involve dose reconstruction for toxic substances—is something that commonly occurs in these types of trials involving exposure and allegations of long latency diseases. It is something that lawyers and parties and judges are familiar with, and it is just a question of getting the appropriate experts up there, getting the information that is available, and using that information to try to reconstruct what the range of dose exposure could have been.

The CHAIRMAN. Just because you reconstruct does not mean that it is credible or accurate.

Mr. WILLMORE. The courts in these cases would make the best judgment possible on what the doses were that the plaintiffs were exposed to. And the courts operate on the preponderance of the evidence standard, with expert testimony available from both sides.

The CHAIRMAN. Of course, as I read the *Jenkins* decision, he seemed to say that they were not credible.

Mr. WILLMORE. That was the opinion of one judge. Again, as I indicated, I would rather not discuss a particular case that is under litigation.

The CHAIRMAN. Sure. Does the Justice Department subscribe to the so-called strong version of the burden of proof which requires that probabilistic evidence be corroborated by some particularistic evidence before a plaintiff can demonstrate his case by a preponderance of the evidence?

Mr. WILLMORE. If by "particularistic evidence" you mean evidence as to the individual, we clearly argue very strongly that before an individual plaintiff can obtain relief, he has to put his case before the court, and not the case of some typical individual who may or may not have the characteristics of the plaintiff who is actually bringing his case.

The CHAIRMAN. What do you mean by that, though?

Mr. WILLMORE. It is the point I was emphasizing in my statement. The probabilistic tables assume an average, typical individual. But the plaintiff may not be average or typical at all. He or she may be very different; may have a totally different history from the type of average, typical person that the tables assume. Obviously, when that plaintiff is bringing a case involving a specific exposure, a specific illness, and a specific personal history, it is that that the court has to consider, and not what may or may not be the case for this hypothetical individual who really does not exist.

The CHAIRMAN. Well, because the data was not collected, what if there is no particularistic evidence such as the cases involving radiogenic cancer causality. Is it your assertion that all these cases ought to be thrown out because the evidence is merely probabilistic?

Mr. WILLMORE. Senator, let me distinguish between two things. The type of evidence that we were just talking about that was not collected, as you put it, was dose information. There is nothing in the PC tables which really tells you anything about the doses or the dose rates to which individuals were exposed. Rather, you put in the dose as an element in the PC calculation. I think that answers your question.

The CHAIRMAN. OK. Is it not true that probabilistic assessments are the basis of all expert testimony, and that it is the very regular probabilistic nature of this testimony that distinguishes it from factual testimony? Experts usually attest to that which is usually true.

Mr. WILLMORE. I think a lot of what experts testify to is, obviously, probabilistic in the sense that an expert is opining on what is more likely than not. But I would say that that kind of probabilistic approach is something common to expert testimony in all areas of tort law. In a medical malpractice case for example, an expert physician witness may testify that it is more probable than not that the plaintiff suffered his injury as a result of this medical treatment.

The CHAIRMAN. Well, are you saying that a personal opinion is better or more acceptable than an elaborate scientific calculation?

Mr. WILLMORE. No. What I am saying is that when you have a specific individual, and you have information as to that individual—his background, other forms of exposure, his occupational history, exposure to other carcinogens—the data as to that individual, and the conclusion that it leads you to, is bound to be more credible as to his claim than some hypothetical person that does not exist.

The probability tables involve a hypothetical individual. When you are trying a case before a court, you are concerned with the data and information about the particular person who is bringing the claim.

The CHAIRMAN. Well, I would content that the radioepidemiological tables involve real individuals. I mean, you say hypothetical individuals, but I think they involve real individuals.

Mr. WILLMORE. Well, I am not sure. Maybe I am not explaining what I am trying to say very well.

The CHAIRMAN. Go ahead.

Mr. **Willmore**. The probability tables are a population based study. They try to make findings as to the broad population. It is a crude analogy, but the tables are somewhat like a poll. For instance, you go out and conduct a political poll, and discover that 60 percent of a particular group favor a particular position. Well, while that is very useful as to that particular group, it does not tell you what a particular person in that group may believe. The PC tables are roughly analogous. They tell you about a particular group, and you can apply that in the sense that you can say, well, if we took the average typical person in that group, that would be the answer. But it does not tell you anything, really, as to a specific person in that group, because that person may have a totally different history from the history of the average, typical person that the PC tables assume.

The **Chairman**. In your experience, Mr. Willmore, have expert witnesses with impressive credentials ever made pronouncements that were not likely to be true, or would not likely have been accepted by the mainstream scientific community, and when the issues are highly esoteric, how do the courts distinguish between real experts and charlatans, and how do the courts know when an expert is exceeding what is warranted by his expertise? And last but not least, is it possible that the NIH report might help the courts to make these difficult assessments?

Mr. **Willmore**. As to your first question about how the courts assess the credibility of experts, that is, obviously, something that any trial judge has to struggle with. Judges are not experts on radiation. They are not experts on medical procedures. They are not experts on a lot of things that come before their courts, and they have to rely—and often, this is something that is left to juries, though not in the case of the United States under the Federal Tort Claims Act because it tries its cases only to the judges—but the finder of fact has to make some credible assessment of which expert is right and which expert is wrong. And looking back to the time when I was a district court clerk and was involved in making those kinds of assessments, I can tell you that what the judges and the clerks and the finders of fact look at are the credentials of the experts—that is, their background, how distinguished they are, how well are they accepted by the scientific or medical community of which they are part. This is all part of putting an expert witness on the stand, and of convincing the finder of fact that that expert witness is credible, has good judgment, represents the mainstream view of his or her profession.

I am sorry, Senator. You had a second part to your question.

The **Chairman**. Well, basically, is it not possible that the NIH report might be helpful to judges in assessing the credibility of certain witnesses.

Mr. **Willmore**. It might be. If someone came in with testimony that was, to use the colloquial, really "off-the-wall", this might help the judge assess whether that testimony was "off-the-wall" or not. But it is only one study. There has been a tremendous amount of research, analyses and studies in the area of low-level radiation already. Plaintiffs, for instance, put a lot of experts on the stand who simply reject, for example, the risk coefficients that are part of the BEIR-III study, a study which was pretty much adopted in the PC tables. Thus, in the trials, we end up having to deal with the challenges by plaintiffs' experts to the BEIR-III risk coefficients.

The fact that BEIR-III is out there, the fact that BEIR-III is one of the most credible pieces of scientific work by a group of eminent scientists in the area, the fact that this has been consistently used by the mainstream in this area, does not prevent plaintiffs from using experts who totally reject those risk coefficients, and it does not prevent the courts from adjudicating whether or not the conclusions of BEIR-III are valid.

The CHAIRMAN. But keep in mind BEIR deals with safety standard questions and not liability-type questions, and I might add that we had three panels yesterday, all of whom said that these radioepidemiological tables are far superior to what the BEIR tables are.

Mr. WILLMORE. Well, the BEIR tables do not really do the same thing——

The CHAIRMAN. Yes, but you have touted the BEIR tables as being highly credible scientific evidence, and yet you are having difficulty giving tbe same degree of credibility to these NIH and National Academy of Sciences tables.

Mr. WILLMORE. No, Senator. BEIR-III, as I understand it, adopts certain risk coefficients. These risk coefficients are part of the NIH ad hoc working group study. I think they may have made some minor adjustments, but basically, the tables use the same risk coefficients. If the BEIR-III risk coefficients are wrong, then frankly, the NIH tables are wrong, because they used those risk coefficients by and large.

Anyone who wants to challenge the tables and who believes that the BEIR-III risk coefficients are wrong can simply challenge the BEIR-III risk coefficients. And that is precisely what they have been doing for the last few years, even though I think the BEIR-III risk coefficients clearly represent mainstream, respected, credible opinion in this area.

The CHAIRMAN. On April 8, the Justice Department attorneys put on a symposium on radiation liability for the Nuclear Regulatory Commission. They produced a text for this session which includes many frankly scathing comments about the work of the NIH tables committee. The following, for instance, is a quote:

> Speculative evidence which should be found inadmissible by courts hearing radiation cases is exemplified by the so-called radioepidemiological tables developed pursuant to the Orphan Drug Act, Public Law 97-414.

Does this statement represent the view of the Justice Department?

Mr. WILLMORE. Senator, I was aware that this was going to be brought up, so I reviewed the briefing book that was used. First of all, I would like to emphasize that on the cover of the briefing book is a statement that says these are the views of the attorneys conducting the proceeding, and not necessarily the views of the Department of Justice.

I think the views of the Department of Justice on this are really twofold, and it may be that there are individual statements here or there that may have been put in more inflammatory terms than I would use. But I think there are two primary concerns. The first is the one that I deal with specifically and at length in my prepared remarks—and that is, you cannot use a PC value as to a specific individual, for specific data, when that PC value only tells you something about a hypothetical person that does not exist.

And, second, there are assumptions and various hypothetical assertions that are made as part of the probability values assigned by the tables which any court will have to consider. Those are set forth in the report itself. And a court which has those values placed before it should, and I think will, look at—I think it is in chapter 7 of the report--what the report states those uncertainties to be. Whether those uncertainties are so substantial that the court does not want to accept the probabilities is something that an individual court will have to determine.

The CHAIRMAN. Well, I point out that the same science that underlies the tables also underlies radiation safety standards. You know, is the science behind the safety standards also mere speculation?

Mr. WILLMORE. No, Senator. I do not think we are arguing that the science is bad. The science is the best science apparently now available. The question is what conclusions do you draw from it. When you are involved in setting health and safety regulations, you have to take the best science you can and draw the appropriate conclusions. That may not be the same way to approach compensation decisions, particularly because health and safety standards deal primarily with the average, typical person, while compensation deals with a specific individual.

So one approach, which is an approach geared to the broad population—involving a hypothetical average, typical person—may be totally appropriate for health and safety standards, but may be totally inappropriate for resolving the claims of John Doe, who can bring before the court data about his personal history, previous exposure, and family history, that may be very relevant in deciding his individual claim for compensation.

The CHAIRMAN. Well, in your testimony, you made much of the point that the tables deal with people who match certain standard profiles, whereas the court has to consider the individual in light of his individual characteristics.

Mr. WILLMORE. That is correct.

The CHAIRMAN. What if nothing relevant can be discerned concerning the effects of these idiosyncracies? Again, I would note that what an expert does is apply a general finding or observation to a specific situation. The tables, it seems to me, may deal with the only reliable factors that can be assessed for any individual.

Mr. WILLMORE. I disagree with that, Senator, and I think there are statements in the report itself which make it very clear that there are a number of characteristics of specific individuals that may bear very much on the likelihood that his or her cancer was caused by radiation. If someone was an x-ray technician for 20 years and exposed to immense amounts of radiation from being an x-ray technician, that might give you a very different assessment than if some body was not occupationally exposed to a lot of radiation over many years. If someone has a long history of leukemia, for example, in their family, that may lead to a very different expert opinion than someone who has no family history of leukemia, assuming the allegation is that leukemia was caused by a particular radiation exposure.

If someone was exposed, and there is documented exposure to a carcinogen, perhaps at massive amounts, that is something that may be very relevant. And I think when you are dealing with specific individuals, it is important to realize that every individual brings his or her fact case and history to the court. That is what our adjudicatory system is very good at doing—ferreting out the facts and making a good decision based on the facts of that individual's case.

The CHAIRMAN. Well, in the view of the Department, what would it take for a radiation cancer claimant to meet the preponderance of the evidence standard that we have in law today? What kind of evidence would he have to produce—or can he meet that standard, because there has been no data collected by the Government that he can rely on, other than what we have in these tables.

Mr. WILLMORE. The data you are talking about is the level of dose, which——

The CHAIRMAN. Well, that is one—it is the pivotal——

Mr. WILLMORE. That is the data that it is alleged the Government should have kept and did not keep.

The CHAIRMAN. That is right.

Mr. WILLMORE. And we are very confident that we have very good methods for reconstructing dose.

The CHAIRMAN. Well, not only level, but intensity, times, number——

Mr. WILLMORE. Again, we obtain the expertise and the help of the best experts, and plaintiffs use their experts as well; We are very confident that we obtain an accurate assessment of the range of dose within which that person was exposed for the particular exposure or exposures that the person is alleging.

The CHAIRMAN. OK. Back to my original question, then. What do these plaintiffs have to do to meet the preponderance of the evidence standard under present law—-or, can they ever meet that preponderance of the evidence standard under the circumstances that you have described here today, where the data has not been kept, and where we have some of the difficulties that we have mentioned here today.

Mr. WILLMORE. We have a very good idea of how much radiation most of these plaintiffs, if not all the particular plaintiffs we are concerned about here today, were exposed to, and it was extremely low-level. We are very confident that it was extremely low-level. Given that low-level exposure, I think it would be very difficult for them to prove to the Department of Justice or to any objective trier of fact that their cancer was proximately caused by the exposure which is the basis of their lawsuit against the Government.

On the other hand, there are clearly situations where if the facts warrant the conclusion, and we would be using experts to help us in this regard, someone could present a claim to the Department of Justice—actually, it would be to the agency through the administrative claims process that is part of the Federal Tort Claims Act—where that claim might very well be granted, or if it went to trial, where it might be settled. I do not think that is unlikely at all, given the right kind of facts. I think it would be very difficult to do in this kind of situation, however, simply because the exposure was so low.

The **Chairman**. Or at least, you feel it was so low, based upon what your experts have told you.

Mr. **Willmore**. We believe very strongly that it was very low, based on what the experts have told us and testified to in court.

The **Chairman**. What you seem to be saying is that in none of these cases, to your knowledge, because of what you perceive to be such low levels of radiation exposure, should any of these plaintiffs really recover.

Mr. **Willmore**. Well, I do not want to say that there may not be an exception here and there.

The **Chairman**. But you do not know.

Mr. **Willmore**. I personally do not know.

The **Chairman**. So your contention is that without exception, because you do not know of any exceptions, that none of these people should recover.

Mr. **Willmore**. I think that for the very low-level exposure cases it is very unlikely that those persons have a cancer that was proximately caused by the particular radiation exposure.

The **Chairman**. Well, the simple fact of the matter is you are relying on some experts, they rely on other experts; there is a wide diversity in between, and the judge in Utah determined that they were right and you were wrong, at least in some of the cases.

Now, be that as it may, the fact is, nobody really knows one way or the other. And like in all of these cases—I do not know how many cases you have tried, but I have tried a considerable number, and I can tell you that I have always had a wide range of expert testimony, in every case where expert testimony was a factor. And in this particular case, it is something that nobody is ever going to really know, because nobody really measured the levels of radiation. But we do know that there are some aberrational facts, statistics, and other general evidence that would indicate that the amount of suffering in these three downwind States was extraordinary in nature, as a general principle. Now, proving that with regard to individual cases, I agree with you, under present law, is a very, very difficult thing to do.

Mr. **Willmore**. Senator, first of all, I disagree with you that there are aberrational levels of cancer. To the contrary—and I did not bring along a letter, but we have put this in writing to Congress in the past, and certainly, argued this position in court and had expert testimony to support it—there is no cancer epidemic in this area. In fact, the level of cancer is lower than in many other areas of the country.

The **Chairman**. Well, if you have a different subject population, too. But it is not lower with regard to that particular subject population. You have a subject population that basically does not smoke, that basically lives certain health rules that normally would cause—and normally and by necessity, statistically and otherwise, has a lower incidence of cancer in most instances. But here, we have aberrational instances of more cancer under that particular subject group.

Mr. **Willmore**. Senator, I have read quite a bit of material on this subject over the last few years. I have never seen anything—

and I am not saying there is not anything out there—except for one study that seemed to suggest a higher incidence of childhood leukemia, which was refuted in an article in last year's Science magazine, that in any way supports that assertion.

The CHAIRMAN. OK. From yesterday's testimony, it is clear that if there is to be recovery in these areas, some sort of prohabilistic method is not only the best method, but may be the only method for assessing causality for an individual radiogenic cancer claim. I realize that I am referring to "cause and effect", but I would hope that this would be the basis for legal causation.

The point is that the scientists feel that a plaintiff can demonstrate his case only if he can demonstrate a probability of causation. But certain facts must be known before this calculation can be made, whatever the formula.

Now, if the dose is unknown, or it cannot be creditably estimated, the probability of causation method is not going to get you very far; it is that simple. Now, how would the Justice Department propose that plaintiffs prove their cases when credible dose data simply do not exist, and there is a wide disparity between expert witnesses in this regard—and more specifically, if the Government was to have been responsible for compiling such data and failed its duty to do so, does the Department feel that some special consideration should be given to the plaintiffs who, as a consequence, are left with the prospect of making a scientifically valid case under those circumstances?

Mr. WILLMORE. Senator, we feel—and I am just repeating myself here—but we feel we have very credible ways for reconstructing the doses. To some extent, the laws of physics tell us what the highest dose could possibly be, because an atomic weapon in a particular case only generates so much radiation, and that in and of itself places a limit. And there are other ways of looking at what we do know from that period of time. It is not as if there is absolutely no information. There is some information that can be used to try to reconstruct a reasonable and credible dose range. And we feel we have done a very good job of that; that we have very credible estimates. So I do not think we have the problem that you have suggested.

The CHAIRMAN. Well, I think it comes back to the same statement I made earlier, that you do not see under any circumstances, based upon the studies that you have made and your expert witnesses have given you, how anybody could recover as a result of the atmospheric tests in the fifties and sixties. It seems to me that safety standards cost money, and so does liability. Both ways, it is costly. But usually, it is the same parties that pay in either case.

Why, then, shouldn't assessments of liability rely on the same sciences that underpin the safety standards?

Mr. WILLMORE. I think it does rely on the same sciences. The question is what conclusions should be drawn from that science. As I indicated, I do not think the science is that different, but the conclusions that can be drawn for the purposes of health and safety regulation may be very different from the conclusions that should be drawn for purposes of compensation, simply because you are dealing with a different kind of use of that scientific information.

The science is the same. It is the conclusions to be drawn from the science that are different.

The CHAIRMAN. Well, I want to thank you for coming in and testifying today. I think it does kind of set the parameters within which the legal cases are being made. And on your side, you see basically no liability, based upon your expert testimony and your assessment of the matter. On the other side, they see tremendous liability. You do not see any reason under the discretionary function to change your assertions here today. The other side feels that you should. And would it be fair to say in conclusion that if there has to be a resolution of this matter—because there is a wide disparity of belief in the matter, whether or not one side or the other is totally right or totally wrong—that the only way this matter could be fully resolved to everybody's satisfaction, or at least for the most satisfaction of everybody, would be if Congress does act statutorily to provide some sort of remedy or some sort of right of recovery—is that a fair comment?

Mr. WILLMORE. It is a fair comment. I disagree with it.

The CHAIRMAN. Well, I know, but it is a fair comment.

Mr. WILLMORE. Well, it depends—if you want to resolve individual claims of personal injury, then I think the only way to do it credibly is through the courts.

The CHAIRMAN. Well, but you are saying that there is no way anybody could meet the burdens of proof under present tort law, without the data that contradicts what you have reconstructed as the data, in order to recover. So if, for instance, you could possibly be wrong here—I know that it may be very difficult to arrive at that conclusion—but you could possibly be wrong and the other side is right, but the law basically favors your position because there is no data, is not then the only remedy available to these people a statutory remedy?

Mr. WILLMORE. It is not the law, Senator, that favors our position; it is the facts.

The CHAIRMAN. Well, I am saying you are saying that, and they say otherwise. I agree. Let me compliment you. I think you are a brilliant young lawyer, and I think you have presented the Government's case about as well as it could be presented here this morning, and I compliment you for that. But I think you are also as a brilliant young lawyer willing to admit that you could possibly be wrong on the facts.

Mr. WILLMORE. Well, I am not making the assessment on the facts, sir. We have experts——

The CHAIRMAN. Well, yes; you are. You just have.

Mr. WILLMORE [continuing]. We have experts, and I am simply giving you the conclusions that have been drawn by the Department on the basis of our experts who have advised us on these issues.

The CHAIRMAN. You seem to be, like your counterparts on the plaintiffs' side, afraid of the statutory remedy here. You see, they believe and sincerely so that they are going to win in the courts. I have grave misgivings about whether they are ultimately going to win in the courts because of, I think, what you have stated, which in many respects is a correct restatement of the law. I question whether the courts are going to be able to continue to sustain some of these cases that have been won on the lower level, because I think you have accurately stated some aspects of the law that really come to bear against the right of recovery of these people.

If, for instance, you are wrong on the facts, or your experts are wrong on the facts—and we always have to admit that there is that possibility—then I do not see why it is so difficult for you to say that the only remedy, if you are wrong, and the experts are wrong on your side, the only remedy that may really exist under those circumstances may have to be a statutory remedy.

Mr. WILLMORE. But who decides if the experts are wrong? That is the question for the court——

The CHAIRMAN. Well, I suspect the Congress is going to have to decide that if we have a statutory remedy, you see, and the Congress is going to have to try and resolve this in a way that may be resolved. You see, one of the biggest problems I have had with it, and one of the biggest problems my constituency has with it—many of my constituents feel that that is a price you have to pay during time of war, and that nobody should recover. A number of constituents have spoken to me in that regard. Others feel that, look, since the Government was so grossly negligent in these situations and did it not do its duty, in fact, not only did it not do its duty, but willfully failed to do its duty, that the Government ought to have some responsibility no matter what, and that the best way of resolving this would be since you cannot pinpoint exactly who got cancer and who did not from the atmospheric tests, at least by any creditable expert testimony—at least, that is the assertion today—then the only way to resolve it would be on a probability of risk theory, based upon scientific tables that have been produced pursuant to the best scientific process, in the best scientific way, for the best scientific purposes, at this particular scientific time.

So, that is what our people out there, a lot of them, feel. And if that is true, and you are correct that there is no way these people can ultimately recover because the courts will overturn the *Allen* decision and all other decisions that are in favor of them, then the only recourse, the only remedy, the only hope for these people, would be a statutory remedy that Congress may or may not in its wisdom choose to enact.

That is a fair statement, isn't it?

Mr. WILLMORE. Yes; it is a fair statement, but one I also disagree with.

The CHAIRMAN. I understand. I did not expect you to agree with me on any aspect of this case today, but nevertheless, it is fair to say that that is what it is going to come down to.

Now, it may be that we will not be able to enact any statute as long as these cases are alive, and it may be that you will be proven wrong, and that these cases will be sustained on appeal. It may also be that that may be due to judicial activism. But that is not an unforeseen consequence in the courts of this land. And if there is ever a case for judicial activism, it may be this case, even though I have trouble with judicial activism myself.

So what I am saying is that you may lose in the end, and it may be a very significant loss, because then you may be confronted with thousands and thousands of cases, many of which you and I both know do not deserve to recover, and some of which do deserve to recover—and some of whom deserve to recover may not recover, and some of those who do not deserve to recover may. So that is one reason why we tried to come up with some reasonable approach here to try and resolve this problem and stop the litigation, which in and of itself, is going to cost millions and millions of dollars, and already has.

I would rather pass that money along to those who feel that they have been wronged and who definitely have been wronged, whether or not they have contracted cancer—and I believe they have—than to continue another two decades of litigation that may not ever resolve this problem and may create more divisiveness and more animosity on both sides.

Well, I want to thank you for your testimony. I think it has been very interesting testimony, and I think it certainly sets the parameters on your side beyond which it may be difficult to go.

But thank you for coming. We appreciate your time.

Mr. WILLMORE. Thank you, Senator.

[The prepared statement of Mr. Willmore and responses to questions submitted by Senator Simpson follow:]

STATEMENT

OF

ROBERT L. WILLMORE
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
DEPARTMENT OF JUSTICE

BEFORE

THE

SENATE LABOR & HUMAN RESOURCES COMMITTEE

AND

SENATE NUCLEAR REGULATION SUBCOMMITTEE

CONCERNING

THE REPORT OF THE NATIONAL

INSTITUTE OF HEALTH AD HOC WORKING GROUP TO DEVELOP

RADIOEPIDEMIOLOGICAL TABLES

ON

JUNE 12, 1985

I am pleased to be here today to present the views of the Department of Justice on the impact of the Report of the National Institute of Health Ad Hoc Working Group to Develop Radioepidemiological Tables on claims filed by persons seeking compensation for injuries allegedly caused by exposure to low levels of ionizing radiation.

The United States presently is a defendant in a substantial number of suits in which the plaintiffs assert that they are entitled to damages for exposure to low levels of ionizing radiation. These suits, which are brought under the Federal Tort Claims Act, include over 4,000 individual plaintiffs. The single largest portion of these lawsuits arise from the atmospheric atomic weapons testing program conducted in the fifties and early sixties, commonly known as the downwind radiation cases. While the radiation exposure suits present numerous and often very different legal and factual issues, our experience, gained through the litigation process, gives us the benefit of direct knowledge of the factors which we believe are likely to bear on consideration of the Report for use in any context involving claims of personal injury.

The touchstone for credible claims resolution must be individual consideration of each and every factor bearing on the plaintiff's condition. Age, weight, family history, occupational environment, exposure to sunlight, smoking, diet, exposure to known carcinogens, and many other aspects of a person's life may bear on causation of cancer, to the extent that causation is ascertainable. The judicial process requires, reasonably enough, that the characteristics of the plaintiff before the court, rather than a hypothetical or "average" person be examined, in order to reach a considered, fair judgment as to causation.

This approach to causation, which applies to all of tort law, is equally applicable to claims alleging injuries due to exposure to low levels of ionizing radiation. As Judge Patrick Kelly recently noted in Johnston v. United States, 597 F. Supp. 374, a case involving allegations of cancers from occupational exposure to low-level radiation:

> We can see that in matters of determining the cancer risk from low occupational doses of radiation, scientists do not deal with what exists in fact and can be measured or experimentally proven. Rather, they deal with theory, hypothesis and assumption. While such an approach is a valid way to set general safety standards, it cannot be used to establish legal cause through mathematical calculations.

Indeed, the Ad Hoc Working Group notes this very point in its Report, when it observes:

> PC calculations based on SEER values for baseline cancer incidence require the assumption that the individual in whom cancer was diagnosed following a documented radiation exposure would have been, in the absence of that exposure, "typical" of the US population for his or her age and sex with respect to cancer risk. But the subject may have had an atypical history of exposure (or nonexposure) to known carcinogens or may have experienced other life events associated with a higher or lower cancer risk than average. Or the subject may be a member, perhaps even a "typical" member, of an ethnic, religious, or other population subgroup known to have cancer rates higher or lower than the U.S. population as a whole. (page 45)

Later, in the same section of the Report, the Working Group concludes:

> Clearly, the problem of calculating PC values in the presence of differences in total cancer incidence because of exposure to other carcinogenic agents, personal history with respect to factors related to cancer risk, or membership in a particular population subgroup, is fraught with uncertainty. (pages 45-46)

Thus, such radioepidemiological tables, while perhaps providing valuable insight on the probability of causation on a hypothetical "typical" person with cancer, will likely have only limited value in the context of the much more extensive and detailed information available on a particular plaintiff alleging injury from a specific exposure. And, as noted, it is our firm belief that any system of compensation, and particularly the tort system, must rely on determinations of causation based on each individual's unique and specific case if it is to be viewed as fair, reasonable and credible.

In emphasizing the inherent limitations of using such probability tables for determing actual causation, I do not wish to overlook the fact that there are uncertainties in the probabilities assigned in the Working Group's Report -- even assuming the "typical" individual could be found -- which would limit their use in determining causation. You have already heard extensive testimony and will be hearing additional testimony on the many assumptions and uncertainties underlying this Report, and I therefore will not detail those uncertainties and assumptions here. I would note, however, the Working Group's own statement that:

> The tables cannot now provide precise measures of the probability that certain cancers have resulted from previous exposures to known doses of ionizing radiation. (page 116)

For this reason, the Working Group cautioned that:

> . . . the tables can be regarded as no more than a guide to causation . . . . (page 79)

In sum, we believe that while the Report is a valuable scientific document which merits careful attention, it is not appropriately utilized as a determinative factor in resolving any individual's claim that exposure to low level ionizing radiation caused his or her cancer.

This concludes my prepared statement. I will be happy to answer your questions.

U.S. Department of Justice
Civil Division

Deputy Assistant Attorney General

Washington, D.C. 20530

August 20, 1985

Honorable Alan K. Simpson
Chairman
Subcommittee on Nuclear Regulation
United States Senate
Washington, D.C. 20510

Dear Senator Simpson:

Enclosed are my answers to your questions for the record regarding my testimony before your Subcommittee and the Committee on Labor and Human Resources on the NIH Radioepidemiological Tables.

Sincerely,

Robert L. Willmore
Deputy Assistant Attorney General

Enclosure

cc: Honorable Orrin B. Hatch
Chairman
Senate Labor and Human
Resources Committee

1. You note in your testimony that the Department of Justice is now defending against various lawsuits seeking compensation from exposure to radiation, involving some 4,000 or so plaintiffs. Please provide a synopsis of what you see as the emerging trends in these cases, as courts deal with the difficult causation issues that radiation poses.

ANSWER:

The most important emerging trend in low-level radiation personal injury litigation is that the courts are becoming more sophisticated and knowledgeable in their analysis of allegations of causal relationships. While there continue to be prominent exceptions in this regard, by and large the courts are demonstrating a willingness and ability to base their decisions on credible scientific and medical evidence. Specifically, there is increasing indication of the following trends in such lawsuits:

- There is a growing awareness that low levels of radiation exposure present no greater health risk than many routine activities such as driving a car or sitting on the beach.

- Many courts now understand that not all cancers are caused by radiation; indeed, that a very small percentage of all cancers are even theoretically attributable to man-made exposure to radiation.

- Courts are becoming increasingly willing to reject the credibility of many plaintiffs' "experts" whose views are considered aberrational and well outside the mainstream of the scientific community.

- Increasingly, courts look to those scientific views that represent the consensus of the mainstream of the scientific community.

We believe that this trend, if it continues, will result in better decisions in low-level radiation personal injury litigation.

2. Are the courts and juries before which you have appeared able to handle the complex issues involving radiogenic cancer in a fair and equitable fashion?

ANSWER:

We do not, of course, appear before juries with any regularity, though occasionally juries are used by judges for advisory purposes. We believe that the courts largely have been able to deal with these complex issues adequately and fairly. To the extent that there are problems (*e.g.*, the "deep pocket" phenomenon), they tend to be problems common to most of tort law and not unique to radiation exposure cases.

3. Is there any clear indication that the principle established in the "Allen" case in Utah--where the burden of proof was shifted to the defendant--is gaining widespread currency in judicial circles, as a means of addressing the causation issues in these cases?

ANSWER:

No. To the contrary, we believe that the burden shifting technique used in *Allen* was aberrational. We are aware of at least two post-*Allen* decisions that have expressly rejected this burden shifting technique: *Timothy v. United States*, Civil No. C-80-0445A (D. Utah, Jan. 16, 1985) (Order Denying Plaintiffs' Motion to Amend), and *Johnston v. United States*, 597 F. Supp. 374 (D. Kan. 1984).

4. What impact would result in the various cases that you are involved in now if the Congress were to mandate that the courts use the probability of causation tables, and the accompanying report, as a "guide" to compensating individual cases?

ANSWER:

The precise impact would depend on how Congress mandated the use of the Tables. As it is, the Tables can be used in litigation, provided the plaintiff or defendant wishes to use them. Most likely, the Tables, if used, would be used to support pertinent expert testimony.

A statutory requirement that the Tables be used would be both confusing and difficult to implement. It is unclear how the trier of fact should use the Tables, particularly if neither plaintiff nor defendant base its arguments on the Tables. Moreover, in our view, the trier of fact should be free to assess the weight of the Tables in its decisions vis-a-vis the other evidence presented at trial. A requirement that the Tables be used could readily lead the trier of fact to give less weight to other evidence which may be as or more probative in the context of the facts of the particular case.

5. If I understand the logic of the "probability of causation" approach to compensating individuals exposed to radiation, wouldn't it be possible, if we endorse this approach, for an individual with, say, a 30% "probability of causation" that his

cancer was caused by radiation to recover 30% of a full award, and then later bring a lawsuit alleging that his cancer was, say, the result of benzene exposure--and, if he could demonstrate a 50% or greater likelihood of that, thereby meeting the normal tort standard, then recover a full award for the benzene exposure? Have we not then compensated this individual for 130% of his claim?

ANSWER:

That is absolutely correct. By its very nature, the probability of causation approach can lead to significant overcompensation.

6. How do you respond to the criticism that has been raised, at the June 12 hearing and elsewhere, that, under normal tort principles, imposing the burden of proof on the plaintiff will result in "undercompensation" of radiogenic cancer claimants, and imposing the burden of proof on the defendant will result in the "overcompensation" of those claimants? To put it differently, is it not very difficult to prove that a cancer *was or was not* caused by radiation exposure under our normal tort principles?

ANSWER:

We believe that application of normal tort principles does not lead to significant overcompensation or undercompensation. While it is true that it is generally impossible to determine whether a particular radiogenic cancer was in fact caused by radiation exposure, the relationship of certain cancers to high-level radiation exposure is well established, and the tort system has little difficulty in awarding compensation in such instances.

The difficulty lies in the fact that many persons have been persuaded or have persuaded themselves--contrary to all current credible scientific knowledge--that low-level radiation exposure is a serious health hazard. Thus, they believe that lack of compensation in these cases must indicate undercompensation. However, where, as here, there is no serious health hazard, lack of compensation represents the correct result rather than undercompensation. The source of the problem, therefore, is not a failure of the tort system, but the fact that the tort system adduces evidence (and bases its compensation decisions on that evidence) that may be directly contrary to the sincerely held but incorrect beliefs of those who seek compensation.

Senator **Kerry**. Mr. Chairman.

The **Chairman**. I am sorry, Senator Kerry. I apologize. I did not notice you were here. Excuse me.

Senator **Kerry**. That is all right.

I would like, Mr. Chairman, if I could, just to introduce a statement for the record. I will not have any questions.

The **Chairman**. Certainly. I appreciate you doing that, and I really apologize for not giving you a chance to question.

Senator **Kerry**. Well, I probably will have to leave before the testimony is over, so I wanted to indicate I do have a statement.

The **Chairman**. Without objection, we will insert your statement at an appropriate point in the printed record.

Also, Senator Grassley has been here, and he submitted a statement for the record yesterday and did not have anything to add to the remarks today, but he had two other hearings that he had to attend this morning and he had to leave. So we will keep the record open through Friday for questions from any other members of this committee to any of the witnesses who have been called before the committee at this time.

Our next panel consists of representatives of the National Committee for Radiation Victims, Mr. Cooper Brown and Ms. Kathleen Tucker.

We are very pleased to have both of you here, and we will be happy to take your testimony at this time.

We will start with you, Mr. Brown.

STATEMENT OF E. COOPER BROWN, PRESIDENT, NATIONAL COMMITTEE FOR RADIATION VICTIMS, AND KATHLEEN M. TUCKER, MEMBER, BOARD OF DIRECTORS, NATIONAL COMMITTEE FOR RADIATION VICTIMS, AND PRESIDENT, HEALTH AND ENERGY INSTITUTE

Mr. **Brown**. Senator Hatch, Senator Kerry, good morning. I would like to introduce myself. I am Cooper Brown, director of the National Committee for Radiation Victims. Appearing with me on this panel today is Ms. Kathleen Tucker, who is the director of the Health and Energy Institute. The Health and Energy Institute is presently in the process, I might add, of producing a radiation law reporter, that hopefully will also help in addressing some of the complex issues that we confront.

Senator, since I have not appeared before you before, I thought perhaps I would briefly introduce myself. I practiced law in a small private law firm for 7 years before becoming general counsel to the National Association of Atomic Veterans, where I worked for approximately 3 years before becoming the director of the national committee. The national committee is comprised of representatives of various victims' groups, such as Janet Gordon with Citizens Call of Utah, and basically serves as a liaison on issues of particular concern to their respective constituencies.

I should also add that we are not here today on behalf of any particular group of plaintiffs' attorneys or constituency, but are here attempting to address some of the issues that are of concern to this committee on behalf of the plaintiffs' bar, as presumptive as that may sound.

The raging debate over the relative risk of developing cancer depending on exposures to varying levels of radiation is one that has not gone unnoticed by the plaintiffs' bar, and I, for one, would like to applaud Senator Hatch for being willing to take a lead in attempting to develop a better undertanding of the relative risks of developing certain cancers as a result of different levels of exposure. I am sure that the Senator must feel at times like the guy who, in an attempt to escape a raging fire jumps into what he thinks is a lake of water, only to find once there that he is stuck in quicksand——

The CHAIRMAN. That is not a bad analogy there.

Mr. BROWN. In fact, I wonder if I may feel that way myself before the end of this panel's testimony because, given the nature of the debate, even Ms. Tucker and I cannot always agree on the issues that we deal with here.

But in any event, I think we all are here because of the underlying concern that we share concerning the radioepidemiological tables, and the issue of justice. Certainly, no one on our side of the fence is contending that all cancers are caused by radiation, and the concept of summarizing scientific knowledge on the relationship of radiation to various cancers appears to be a favorable idea.

We were hopeful that the tables mandated by the 1983 Orphan Drug Act would provide a useful guide in evaluating the probability of radiation causation that would aid both the radiation victims and their attorneys in evaluating potential claims for injury. I might add, at the time that this legislation was enacted, I was serving as the general counsel for the atomic veterans, and we at that time applauded this effort to try and get a handle on this issue.

Unfortunately, at this point in time, we believe that the procedures and the criteria used to establish the Rall committee have resulted in establishing a biased panel, as was mentioned yesterday, and in turn, that that has resulted perhaps—unintentionally—in having the effect of developing tables which underestimate the radiation risks.

Admittedly, justice is an elusive goal, and we recognize that the two committees holding these hearings share our goal of achieving justice, or these hearings would not have been held. We hope that these hearings will serve as a basis for further steps that could move us closer to the goal of true justice for radiation victims.

Many radiation victims are currently seeking compensation in State and Federal courts through the tort system. Under the tort system, both plaintiffs who claim injury and defendants charged with responsibility for injury are given opportunities to present evidence and witnesses to the factfinders. It is our understanding that the idea behind the tables was to simplify the often laborious and expensive process of bringing forth witnesses and evidence in radiation cases by providing a summary of the scientific research in the form of radiation risk tables. However, we do not feel that the present tables embody that goal. Instead, the tables appear to reflect the opinions of expert witnesses for defendants in radiation litigation, advocates for the nuclear industry, and scientists who might at best be regarded as neutral on the issue. Plaintiffs' expert witnesses and scientists who have publicly challenged current Federal radiation exposure standards were excluded both from the panel and from the review process. Use of the tables to determine the right to compensation would be tantamount to holding a trial on a radiation claim and only allowing the defendants to offer testimony. In fact, we do not think at this point in time that the interests of justice would be served by using the present tables for anything more than a guide to the literature on radiation health effects.

With that, I would like to briefly address certain concerns that have been raised, because I think a misunderstanding has developed, at least in terms of what we have been trying to convey to this committee.

For example, with respect to the makeup of the Rall committee, with the exception of a couple of people that serve on that committee, it is really not a question of the fact that these people are on the committee, that these scientists were chosen, but the fact that the experts who have represented the plaintiffs in litigation are not on the committee or on the oversight panel. Let me give you an example of what I mean:

On the Rall committee, we have Dr. Yalow, of whom no one seems to be in disagreement concerning her qualifications or lack thereof. Dr. Upton has at times appeared as a defendant's witness in cases in radiation cancer claims. He was one of the defendant's witnesses in the *Allen* case, and he was also one of the defendant's witnesses in the case, *Dennis* v. *General Electric.*

Dr. Land was one of the defendant's witnesses in *Allen* v. *U.S.A.*, and Seymour Jablon, who also serves on the Rall committee, was listed as a Government witness in the *Allen* case, but not called to testify. I might add that Mr. Jablon was and still is a member of the Government's Dose Assessment Advisory Group, which was charged with developing evidence to dispute plaintiffs' experts in *Allen*. In fact, in the *Allen* case, I believe some of the DAG's minutes that came forward contained therein representations by Mr. Jablon where he stated to the effect: "Our job is to refute the witnesses in the *Allen* case." And since Mr. Jablon is still a member of the DAG's and still involved in that process, it starts raising some real concerns on the part of the plaintiffs' bar.

So our argument is not—with a few exceptions, which Ms. Tucker will talk about—that these people should not have been involved; our argument is that if Health and Human Services included the defendant's experts, the plaintiffs' experts should have been included as well.

I should also add plaintiffs' counsel in the Allen case were not able to appear. In fact, that is probably why Ms. Tucker and I were invited. But I do understand that they have a very negative attitude at this point toward the approach now before you. In fact, it is safe to say that those in the plaintiffs' bar familiar with the tables are very concerned at this point in time.

The concern is this, that this committee's endorsement of the present risk tables in effect establishes a Health and Human Services seal of approval on the tables and what they have to say about risks of radiation at low levels.

The **Chairman**. But you have brought up an important point. There is so much criticism from the plaintiffs' bar, why aren't they here? We have invited them to come. It seems to me this is the place to make their case, and yet they all basically either were out of town or refused to come. Don't you think it is important that they come and testify and give us their viewpoints with regard to these matters, because that is what I am interested in. If there is something wrong with what has happened here, it seems to me the plaintiffs' bar would be right here, telling us what is wrong.

Mr. BROWN. Well, I do feel it is important. In fact, that is why we are here, because when we learned that Mr. Udall had a conflict, and as I understand it, had to be in England during this period of time——

The CHAIRMAN. Yes, he did say to us that he had—but there are a lot of other attorneys out there who are equally important in these cases, who are very aggressive in pushing the cause of the plaintiffs in these matters, and who we feel would be very creditable and important witnesses here, and I want to know why they are not here.

Mr. BROWN. Well, I am afraid that with the exception of Mr. Udall, you would probably have to ask them. Realizing——

The CHAIRMAN. We did ask them, and a lot of them just refused to come.

Mr. BROWN. Yes. In my situation, realizing the importance of these tables, I talked with your staff and asked Mr. Udall if he would mind if we appeared in his stead, because it looked like there would be no one here addressing some of these concerns.

The CHAIRMAN. Well, that is right. And one of the things that bothers me is—you know, the Justice Department was not grateful for the opportunity to come and testify, but at least they did—and as much as I disagree with their conclusions, at least they came and testified and explained why they have reached the conclusions that they have and justified their position. Whether you agree with it or not is another matter, but they at least came. Now, it seems to me that it would have been very helpful here had the plaintiffs' lawyers been willing to come in and tell us why the Justice Department is wrong, and why these particular points that they are making are just plain not good points.

Now, I do not know what to do. It is very difficult to make their case for them, since they are the people who have to come in and make it. I am disappointed that they did not come.

Mr. BROWN. The only thing I can say—and I do not know if this is telling tales on my brethren at the bar or not—but it seems to me that I have noticed that attorneys who are heavily involved in the litigation process often do not recognize or appreciate the significance of legislative activities that are in some way related to what they do.

The CHAIRMAN. Well, that is surprising to me, because I think an awful lot of the evidence they had, an awful lot of the impetus that they had in court, especially in the *Allen* case, came from these very hearings, came from the materials that we were able to get them, came from the disclosures that came through the investigations that we have done. And it seems to me that the least they could have done was show up here at these hearings and help us to establish at least their side of the case, so that my colleagues in the Senate and in the House of Representatives could make some value judgments here concerning just what should be done. Now, I do want to say that I appreciate you and Ms. Tucker coming in and representing them, but I think it would have been even better—we still would have wanted both of you to testify, but it still would have been better had they come in and testified.

Now, not only have they not testified, but at least the few that we have chatted with who have been willing to speak about it have said they do not particularly like the idea of having a trust fund set up on the Micronesian compact, which is something I think may be the way to solve this problem once and for all, and get rid of all of the divisiveness and see what we can do to provide a mechanism, a procedural means whereby people can be compensated, and there will be a set limitation to whatever the Federal Government's exposure is, at least in this downwinder cases.

Mr. **Brown**. In fact, in a few minutes, I would like to address that particular issue. If I may, I will get back to concluding these particular points and then try to address that particular issue.

Returning to our concern about what the effect of these hearings and the tables that have been produced by HHS would have, with respect to the debate in the courts and before the agencies on the relative risks of radiation exposure, the concern, then, is that we have here an official Government endorsement of a group of scientists and views that have not been well received in the courts. We believe that this will most assuredly be used to legitimize their views to the detriment of fallout victims and other radiation victims.

I want to stress this point because it was alluded to by the Senator this morning in your opening statement, in which you say, "At the very least, the courts and the workers' compensation boards should have some guide to evaluate the credibility, the expertise, and the testimonies of expert witnesses." Well, in fact, what we have here is a panel and a group of the defendant's witnesses who are establishing criteria that will then be used against the plaintiffs' expert witnesses when we go into trial. I think this is going to have a very serious and detrimental consequence to fallout victims as well as other radiation victims.

Moving on, the question came up yesterday about the objectivity of the National Academy of Sciences Oversight Committee and wasn't that sufficient for peer review. I think there is an important point again to be made. The makeup of this group does little to convince us of their impartiality or objectivity.

I have just been passed a note; Ms. Tucker wants me to make sure I leave some time for her, and I certainly will.

It is not so much whom these people work for, as to what they have also done in particular cases. For example, Dr. Saenger has testified against the plaintiffs in the *Allen* case, in the *Johnson* v. *U.S.A.*, in *Dennis* v. *General Electric*, and in the *Krumbach* workers' compensation case. Dr. Ed Webster has been a defendant's witness in *Dennis* v. *General Electric* and is on the list of experts in both the *Johnson* case and the *Allen* case. Dr. Jacob Fabrikan was a defendant's witness in the *Johnson* case.

As we point out in our written testimony, this lack of impartiality is a continuous problem, even when the NRC has been called to do studies such as was done to assess the viability and validity of doing an epidemiological study of multiple myeloma among the occupation force veterans that went into Hiroshima and Nagasaki. That NRC report was challenged by eminent doctors such as Dr. Bernard Greenberg, a biostatistician and dean emeritus at the University of Northern Carolina School of Public Health, and Dr. Edward Radford, whom we all know. In fact, in Science magazine, which ran an article about this whole issue in 1983, they noted that:

> At each step of the way, the NRC's method is contributed to an under-estimation of the observed and an over-estimation of the expected number of cases of multiple myeloma, making it less and less likely that an excess would be detected. Even if it did exist, the NRC's conclusion that there is no excess of multiple myeloma is not supported by the analysis.

In fact, Science magazine noted that when the NRC was asked about this, they acknowledged that their report was intended from the outset to serve primarily political purposes.

In fact, when Mr. Jablon was asked if the report was sound science, he stated, "I do not think I want to answer that question."

Thus, our difficulty in embracing either the Rall committee's report or the stamp of approval that has been given by the oversight committee results from these direct experiences.

But what of the effects of the tables, if used? This, Senator, is an extremely important point. We applied the risk tables to the *Allen* decision to find out what the consequences would be. What we found was rather startling. At a 10-percent probability, and using the Tamplin external dose figures, because they would be higher than the internal penetrating doses used in the risk tables, we found that only 4, possibly 6, and at most 7, of the 24 cases that were brought in the *Allen* decision would have been awarded under the risk tables. In other words, between 40 and 60 percent of the people who received judgment in their favor in the *Allen* decision would have been compensated had the risk tables been in place; at a 50-percent probability cause, 2 and possibly 3 of the plaintiffs would have received compensation.

The CHAIRMAN. Mr. Brown, let me interrupt for a second. I have been called to the floor. The Legal Services nominees' confirmation is up on the floor, and I have to manage the floor at that time. So I have asked—and I certainly appreciate my colleague, Senator Simpson, to be here, and he is going to try and finish and complete these hearings.

Let me just say that I feel badly having to go at this particular time, because this is very important to me. But I will review the transcript and look at exactly what your testimony is. I have copies of it, and I have read those, anyway. But I am very interested in how these hearings turn out. I am disappointed that we do not have plaintiffs' lawyers here, because I think that would be very helpful. And we may have to somehow or other see that they get the opportunity of being heard again, if they can come. But in any event, I think we have set some real parameters here, and your testimony is helpful, as well.

And I apologize to you, Ms. Tucker, for having to leave, but I had better get over there and manage the floor.

I thank you, Senator Simpson, for being willing to continue this hearing.

Senator **SIMPSON** [presiding]. Thank you, Orrin, for your willingness to proceed as you have over these months.

I would ask you, Mr. Brown, how long have you been testifying?

Mr. **BROWN**. Well, actually, I was about to ask how much time we have remaining.

Senator **SIMPSON**. Well, you do have time. I want to be sure that your position is expressed. That is important in these proceedings.

How much time has been consumed?

STAFF. About 20 minutes.

Mr. **BROWN**. I thought it was 5.

Senator **SIMPSON**. It seemed like 5 to you, didn't it? That's the way it is. That is why we have this light system up here.

Ms. Tucker, how long did you wish to testify?

Ms. **TUCKER**. Several minutes.

Senator **SIMPSON**. Several minutes.

Mr. **BROWN**. That probably means 10, 15—any time you ask an attorney———

Senator **SIMPSON**. It may mean more than that in my vernacular.

All right. If you could perhaps wind up your remarks in about a very few minutes, and then we will try to extend some time to Ms. Tucker, and then I have some questions, and we will develop some dialog here.

Mr. **BROWN**. I will jump over some of this, but first, I will repeat the point I was just making. We applied the risk tables that are before this committee to the *Allen* case, and using two different probabilities of causation, one at 10 percent and one at 50 percent, we found that in both situations, the number of plaintiffs that would prevail using the risk tables was actually less than those who actually, in fact, did prevail before the Federal court. I might add that we attempted in every situation to lean over backward to try to give the benefit of the doubt to an award under the risk tables.

The other thing which might be of particular interest to you, Senator, is that we looked at the effect of these tables on the VA claims process for atomic veterans. We understand the Veterans' Administration is talking with the Keyworth committee about using these risk tables in evaluating claims by veterans that were in nuclear weapons tests. Interestingly, we surmised the following: That out of the eight leukemia cases that have been awarded by the Board of Veterans' Appeals to atomic veterans that were in nuclear weapons tests. With the tables in place at a 10-percent probability of causation, we found that only four of those cases would have won, at a 50-percent probability, possibly one of those cases would have won.

So finally, I want to turn to———

Senator **SIMPSON**. If you could, please—I am really in a crush. I am going to get struck down soon after 12:15, and I would like to conclude, and I assure you that your remarks and whatever you wish to amplify will be in the record. But if you would please conclude in about a minute, we will go to Ms. Tucker.

Mr. **BROWN**. Well, I will conclude in a second, and at this point, turn it over to Ms. Tucker.

Senator **SIMPSON**. Thank you very much.

[The prepared statement of Mr. Brown follows:]

NATIONAL COMMITTEE FOR RADIATION VICTIMS

TESTIMONY OF E. COOPER BROWN, ESQ. & KATHLEEN M. TUCKER, ESQ.

BEFORE

THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
&
THE SUBCOMMITTEE ON NUCLEAR REGULATION OF THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

JUNE 12, 1985

Good morning, Senators. My name is E. Cooper Brown, and I am the President of the National Committee for Radiation Victims and former general counsel for the National Association of Atomic Veterans. With me today is Kathleen M. Tucker, a member of the board of directors of the National Committee for Radiation Victims and president of the Health and Energy Institute, which is conducting Radiation Litigation Seminars and will soon produce a Radiation Law Reporter. We are both attorneys, and we appear today on behalf of the plaintiffs bar. We thank you for the opportunity to present our comments on the Radioepidemiological Tables which could have an impact on thousands of claims for radiation injury by those living near the Nevada Test Site, nuclear weapons facilities, or nuclear power plants, as well as on atomic veterans, nuclear workers, uranium miners, medical radiation workers, and others exposed to ionizing radiation.

The underlying concern we all share in regard to the Radioepidemiological Tables is the issue of justice. We certainly do not contend that all cancers are caused by radiation, and the concept of summarizing scientific knowledge on the relationship of radiation and various cancers appeared to be a favorable idea. We were hopeful that the tables mandated by the 1983 Orphan Drug Act would provide a useful guide to evaluating the probability of radiation causation that would aid both radiation victims and their attorneys in evaluating potential claims for injury. Unfortunately, the procedures used to establish the "Ad Hoc Committee to Develop Radioepidemiological Tables" resulted in establishing a biased panel which we believe has developed Tables which underestimate radiation risks.

Justice is often an illusive goal. We understand that these committees share our goal to achieve justice, and we hope that these hearings will serve as the basis for further steps that could move us closer to the goal of true justice for radiation victims. Many radiation victims are currently seeking compensation in state and federal courts through the tort system. Under the tort system, both plaintiffs who claim injury and defendants charged with responsibility for injury are given opportunities to present evidence and witnesses to the fact finders. It is our understanding that the idea behind the tables was to simplify the often laborious and expensive process of bringing forth witnesses and evidence in radiation cases by providing a summary of the scientific research in the form of radiation risk tables. We do not feel that the present tables embody the goal. Instead, the tables reflect the opinons of expert witnesses for defendants in radiation litigation, advocates for the nuclear industry, and scientists who might at least be regarded as neutral on the issue. Plaintiffs expert witnesses and scientists who have challenged current federal radiation exposure standards publically were excluded both from the panel and from the review process. Use of the Tables to determine the right to compensation would be tantamount to holding a trial on a radiation claim and only allowing the defendants to offer testimony. We do not think that the interests of justice would be served by using the present tables for anything more than a guide to the literature on radiation health effects.

The U.S. federal government cannot claim an admirable record on warning its citizens about the hazards of ionizing radiation. Instead, the federal government urged citizens to go out and watch atomic detonations, rather than urging them to take shelter from fall out. In the decision of Allen v. U.S.A. Federal Judge Bruce S. Jenkins states:

> Considered as an evolving whole, the public education program in off-site communities was consistently heavy with confident reassurances. Important information concerning both risks and effective precautions was scarce at best, and largely ineffective as a rule...
>
> At the most fundamental level, the Government's failure to educate, to inform and to warn deprived those people living in the off-site communities of Utah, Nevada and Arizona of an opportunity -- the opportunity to protect themselves, at least as far as was practical; the opportunity to evaluate the question of risk for themselves and their children; the opportunity to choose to leave the area of increased risk, or to choose voluntarily to stay. Allen v. U.S.A., U. S. District Court, District of Utah, Central Division, No. C 79-0515-J at 313-315 (May 10, 1984).

Federal activities went even further to reassure citizens about atomic fallout. In the spring of 1953 thousands of sheep were lost downwind of the Nevada Test Site following atmospheric atomic tests. Congressional hearings held in 1979 revealed that the federal government engaged in a concerted effort to disregard and to discount all evidence of a causal relationship between exposure of the sheep to radioactive fallout and their deaths. Judge A. Sherman Christensen, who had originally denied compensation to the sheep ranchers in federal court, ruled that a fraud had been perpetrated on his court and reopened the case in August of 1982. That case is now on appeal. Two of the researchers involved in the sheep case fraud upon the court were later placed in charge of studies into the radiation health effects on nuclear workers at Department of Energy facilities.

When scientists warned that atmospheric fallout would lead to thousands of deaths, the Atomic Energy Commission asked Dr. John Gofman and Dr. Arthur Tamplin to study radiation health effects at Lawrence Livermore Laboratory. When the researchers warned that if the average exposure of the U.S. population were to reach the allowable 0.17 rads per year there would in time be an excess of 32,000 cases of fatal cancer plus leukemia per year--year after year--and urged a tenfold reduction in allowable radiation exposure, they were drummed out of government employment. They found their papers censored, their budgets cut, their staff removed, until they finally left the Atomic Energy Commission employment. These researchers were clearly being punished for warning of radiation dangers and challenging federal radiation policy.

Dr. Thomas Mancuso, an industrial hazards epidemiologist, also found his funds cut when he refused to downplay radiation hazards. Atomic Energy Commission officials demanded that Dr. Mancuso sign a press release denying a cancer increase uncovered at the Hanford site by a Washington state public health physician, Dr. Samuel Milham. When Dr. Mancuso refused, his contract officer, Dr. Sidney Marks, initiated the paperwork to prevent authorization of future research funds. Dr. Marks then left the Atomic Energy Commission to take over the Mancuso study. Dr. Marks was involved in the fraud upon the court in the Utah sheep case.

Later Congressional hearings revealed that Dr. Mancuso had received favorable peer reviews, suggesting that his work be expanded, except for Dr. Sidney Marks. Before all funds could be terminated, Dr. Mancuso enlisted the aid of reknowned epidemiologist Dr. Alice Stewart and her statistician George Kneale. They published a paper indicating increased risks of bone marrow cancer (multilple myeloma), pancreatic cancer, and lung cancer for workers who received allowable doses under federal standards. The Atomic Energy Commission successor agencies tried to confiscate Dr. Mancuso's data base, and then circulated substantially less complete data to other researchers seeking to refute the Mancuso findings.

Dr. Irwin Bross of Roswell Memorial Institute was studying potential radiation damage from medical procedures in the Tri-State Survey. He criticized the use of mammographies, warning that their high exposures would cause more cancers than they cured. A peer review committee of radiologists urged an end to his funding, even though they lacked credentials as epidemiologists. Dr. Bross' challenge to federal radiation standards resulted in an end to his federal funding.

Because of these examples, it would not be surprising if federally funded researchers felt that challenges to federal radiation standards might result in economic reprisals. Against this history of federal suppression of radiation dangers, it is important that radiation risk tables be prepared by scientists of the highest integrity if they are to achieve public acceptance and avoid court challenges.

The panel chosen to serve as the "Ad Hoc Committee to Develop Radio-epidemiological Tables" was challenged by radiation victims organizations soon after they learned the panel composition. The panel contained three scientists who testified against radiation victims on behalf of the federal government, Dr. Seymour Jablon, Dr. Arthur Upton, and Dr. Charles E. Land. The panel contained none of the experts who testified on behalf of plaintiffs in the Allen v. U.S.A. case or other lawsuits. It appeared that the federal government hoped to limit liability for past radiation actions by downplaying current radiation health effects.

This fear was confirmed when Dr. Seymour Jablon coordinated a study of atomic veterans who were early entrants to Hiroshima and Nagasaki after the atomic bombings in 1945. *Science* magazine reported that the study "was intended from the outset to serve a primarily political, not scientific, purpose." (SCIENCE, v. 221, no. 4612, p. 733, Aug. 19, 1983). The National Association of Atomic Veterans challenged the study and persuaded members of Congress to ask for a review by the Office of Technology Assessment (OTA) because the researchers had not even contacted all of the multiple myeloma victims already identified through the work of the Hiroshima/Nagasaki Veterans. Although the Jablon study concluded that no unusual levels of bone marrow cancer were found among former U.S. servicemen who entered the atomic-bombed cities of Hiroshima and Nagasaki after World War II, the OTA Review found that the study did not support the conclusion.

> Except for assuming a population at risk of 20,000, at each step of the way the Council's methods contribute to an underestimation of the observed and an overestimation of the expected numbers of cases, making it less and less likely that an excess would be detected, even if it did exist." *

A reasonable person might easily conclude that the Jablon study was lying and cheating. A reasonable person might conclude that they could not trust Jablon to provide honest answers about radiation health damage to atomic soldiers or others. If political motivations might sway one study, couldn't it sway others?

Dr. Rosalyn Yallow was appointed to replace a panel member suffering from poor health. Dr. Yallow has made such biased and inaccurate statements as "There is absolutely no evidence that low levels of radiation are harmful to human health," and "Low level radiation is safe," despite universal agreement among reputable scientists that there is no "safe" level of ionizing radiation. Dr. Yallow went so far as to suggest that Utah citizens "are the healthiest in the nation, and if anything, it seems as if the radiation is good for you."

Scientists who have denied radiation dangers or sanctioned improper studies to hide radiation effects have no place on panels developing radiation risk tables. Yet these scientists were chosen and scientists who warn of

---

*OTA Staff Memorandum, Review of the Report on Multiple Myeloma Among Hiroshima/Nagasaki Veterans, p. 22 (Dec. 17, 1983).

higher than predicted cancer rates from current federal standards were excluded, as were scientists who have testified on behalf of radiation victims.

The composition of the National Academy of Scientists oversight panel does not overcome the problems of the Rall panel. Once again, three members of the panel have testified on behalf of the government or the defendant in radiation claims, while none of the experts testifying on behalf of radiation victims were included. Dr. Saenger, Fabrikant, and Webster have all testified for the defense, but the presence of Dr. Saenger on the panel is bound to undermine public confidence.

In 1978 Congressional Hearings Congressman Doug Walgren stated:

> Dr. Saenger's experiments read like something out of Frankenstein. There is no getting around that. The relationship between Dr. Saenger and the Department of Defense seems quite clear, at least to great parts of the public who have to rely on the results of your study.*

Congressman Walgren was referring to Department of Defense financed studies conducted by Dr. Eugene Saenger at the University of Cincinnatti in which cancer patients were exposed to total body irradiation to gather data on how soldiers might fare on the nuclear battlefield. The subjects were 87 cancer victims who were poor (84 out of 87 were charity patients), mostly black (61 out of 87), with little education (mean education 5 years). Most of the patients were clinically stable, and many of them were working daily, but after whole body irradiation treatment of up to 250 rads, 25 out of 87 patients died within 60 days. Through the years of this experiment using doses up to the 250 rad range (when doses between 250 and 300 were expected to be lethal for half the people so exposed), there was no indication of therapeutic value in reports filed with the Pentagon.

*Effect of Radiation on Human Health, Hearings before the Subcomm. on Health & the Environment of the Comm. on Interstate and Foreign Commerce of the House of Representatives, 95th Cong., 2nd Sess. p. 809 (Jan. 24-Feb. 28, 1978).

Although patients were told that their radiation exposures would help their sickness, The Junior Faculty Association of the University of Cincinnati condemned these experiments, saying:

> ...we have come to the conclusion that many patients in this project paid severely for their participation, and often not knowing that they were part of the experiment. We feel that the evidence clearly calls into question the manner in which these human experiments were designed and carried out. (Junior Faculty Association report cited in Drug Research Reports, v. 15, no. 7 at S-21, Feb. 16, 1972).

Diagnosis of cancer does not strip a citizen of his or her right to the best available medical care, yet Saenger apparently felt justified in pursuing these experiments because the patients were eventually going to die of their diseases and the federal government wanted the information being provided. Death was apparently hastened by the radiation exposures, and seven subjects died within 20 days of the radiation exposure, when bone marrow damage from radiation peaks.

Civilized societies label such human experimentation barbarous, since the treatments were not intended to aid the victims and many were not even informed of the experiments. Would a reasonable person trust the advice of someone who engages in such experimental research? We think not.

It is not surprising that tables developed by scientists whose views range from neutral to defensive of radiation mitigate projected radiation risks. We have requested that some of our scientific advisors review the Tables, and we have forwarded copies of the Tables at our own expense when we learned that the Tables had not been forwarded by the Committee or the panel. We await their detailed comments, but we want to make the following points about the tables:

1. The Tables rely primarily on data from studies of groups exposed to high doses of radiation over a short period of time. More recent studies of people exposed to low doses of radiation over long periods of time have been ignored or discounted without adequate explanation. It is quite possible

that different biological mechanisms are at work. For example, high dose exposures in a short time period may cause greater damage to the bone marrow, resulting in leukemias as found in A-bomb survivors. Lower doses may be more likely to cause solid tumors as found in Hanford workers. Excluding the authors of studies evaluating people exposed to low doses could have been compensated for by including their findings in the formulations, but some recent studies are not even cited in the footnotes.

2. The A-bomb survivor studies are one of the main sources of data used by the panel. Although panel members admit that dose reevaluation for A-bomb survivors will lead to significant increases in risk estimates (They cited increases ranging from 50% increases to 250% as possible), the panel wants the current underestimations of risk embodied in the tables to become the standard risk estimates for the next five years.

3. The formulas developed would have the effect of denying compensation if applied to some of the cases already decided in favor of radiation claimants. For example, if these tables were applied in the Allen decision, at a 10% probability level only six out 24 plaintiffs would prevail, instead of the ten granted compensation. At a 50% probability level, two might have prevailed, giving the most favorable construction, The fact finder in the Allen decision heard arguments from both sides. If the Tables became a legislative remedy, there would be no opportunity for the plaintiff to prove his or her claim.

The Tables could be used in other arenas, like the Veterans Administration. Out of eight leukemia cases awarded compensation by the Board of Veterans Appeals, the 10% probabilty level would have allowed compensation for half of the eight awards, and at the 50% probability level none would have won.

4. BEIR III states that seven other cancers can be expected for each radiation induced leukemia, while the Tables suggest only three cancers for each leukemia. This trend to reduce the number of expected cancers is not justified within the report and further raises public concern over the objectivity of the report

5. Dr. Rosalie Bertell pointed out that the tables use a mathematical formula which requires that a doubling dose for a cancer be attained before the probability of causation can be more than 50%. In other words, a dose expected to double the risk of cancer would have to be reached before the common "preponderance of the evidence" standard could be shown by a claimant. This clearly places a far greater burden on plaintiffs than is warranted.

6. The proposed updating of the tables every five years would prevent claimants from benefitting from new research as it is produced. Studies which might show increases in lung cancer among folks living near a nuclear test site, appearing the year after a review, would not be considered for another four years. Claimants may have cases decided before the panel could incorporate the information. (This assumes that a newly constituted panel will consider low dose studies, as a responsible panel would.)

Although radiation victims organizations were told they could have their say at spring hearings when they requested an opportunity to testify at hearings of this Committee last fall, we were specifically warned not to bring any radiation victims to the table at this hearing. We know that several victims organizations wanted to testify, and still do want to testify. The nuclear industry and the federal government, defendants in radiation litigation, have been provided an ample opportunity and more time than we to present their views. We strongly protest the exclusion of radiation victims from this process as undemocratic and unjust.

RECOMMENDATIONS

In light of the concerns that have been raised by the various witnesses to these proceedings before this Committee, we would recommend several actions that should be undertaken at this time:

1. The Office of Technology Assessment should be asked to investigate the process by which Ad Hoc Committee members were selected and to advise this Senate Committee about the issues and concerns that have been raised about the present Tables.

2. The tables and methodology developed by the Ad Hoc Working Group for Health and Human Services should be submitted to public comment by publication in the Federal Register for review pursuant to the requirements of the Administrative Procedures Act. (See attached memo on APA, which discusses how these Tables constitute "legislative rules" subject to the APA.)

3. An additional half-day of hearings should be held before this Senate Committee to begin redressing the favoritism shown to radiation defendants by allowing radiation victims and independent scientists an equal opportunity to be heard and to assist this committee with their expertise and concerns.

4. A more balanced panel should be appointed after deficiencies in the process have been identified and after consultation with all interested and concerned parties. In the meantime, the Tables should be placed "on the shelf," with it being made explicitly clear by this Committee that the tables and the report are not to be used before any tribunal adjudicating radiation cancer claims.

We have appended curriculum vitae for Dr. Alice Stewart, Dr. Rosalie Bertell, and Dr. Karl Morgan, along with a brief summary of Dr. John Gofman's accomplishments. We think their qualifications merit far more scientific credibility than some of the panel members or NAS oversight members. We demand equal access to the process of decision making for both sides of this controversy. Those truly interested in justice for radiation victims will support this demand for fairness. Those interested in promoting the interests of the radiation industries or in limiting the liability of the federal government for radiation damage will not support us. Senator Hatch, we hope that you will choose to side with your own constituents and get this process opened up so that justice has an opportunity to prevail.

NATIONAL COMMITTEE FOR RADIATION VICTIMS

June 3, 1985

APPLICABILITY OF THE A.P.A. RULE-MAKING REQUIREMENTS TO THE RADIOEPIDEMIOLOGICAL RISK TABLES

I. Summary:

The mandate to Health and Human Services under the 1983 Orphan Drug Act was not only that the Secretary of HHS "devise" radioepidemiological tables, but that they be "published", and published along with a compilation of formulas for determining "the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose" of radiation. (P.L. 97-414, §7(b)) Moreover, the legislation required that both the tables and the formulas "be devised from the best available data... most applicable to the United States,... and in accordance with the best available scientific procedures and expertise." id.

These tables and formulas have now been completed. However, it is the conclusion of this memorandum that -- given the purpose and intent of §7(b), as well as the practical effect of the tables for determining relative risks of radiation-induced cancers among those exposed to radiation -- the product of HHS's work constitutes "legislative rules" issued by a federal agency within the meaning of the Administrative Procedures Act (APA). As a consequence, HHS is required to comply with the rulemaking procedures of the APA -- which among other things requires publication in the Federal Register and an opportunity for public comment.

II. The Rulemaking Requirements of the APA:

The Administrative Procedures Act (APA), 5 USC §553, requires that the public be given notice and an opportunity to comment on legislative rules issued by federal agencies. The APA "broadly defines an agency rule" and "provides only limited exceptions" to the notice and comment requirements. Batterton v. Marshall, 648 F.2d 694, 700 (D.C.Cir. 1980). There must, in fact, be advance notice and comment for all agency rules except "interpretatives rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 USC §553(b)(3)(A).

Rigid categories or formulas that attempt to distinguish legislative from exempt rules do not exist. Rather than engage in "semantic play", the D.C. Circuit Court of Appeals has looked to the "underlying purpose" of section 553 of the APA to determine whether an agency action constitutes a legislative rule:

> The essential purpose of according §553 notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies. Batterton v. Marshall, 648 F.2d at 703.[1]

In fact, public participati n has been held particularly important in controversial scientific areas like exposure to dangerous environmental substances:

> Especially in the context of health risks, notice and comment procedures assure the dialogue necessary to the creation of reasonable rules. National Association of Farmworkers Organizations v. Marshall, 628 F.2d 604, 621 (D.C.Cir. 1980). 2/

This functional approach to whether agency action is a legislative rule depends on several considerations. Where, as in the instant situation, the agency is operating under a Congressional delegation of authority, the courts have looked to the "practical purpose" of the action in question. See Batterton v. Marshall, 648 F.2d at 704. This practical approach looks to both the intent and the effect of the challenged action.

In evaluating "intent", the administrative agency's own labels are indicative but not dispositive. The guiding principle is that "it is the substance of what the [agency] has purposed to do and has done which is decisive." Chamber of Commerce of U.S. v. OSHA, 636 F.2d 464, 468 (D.C.Cir. 1980).

Whether the action has the effect of an exercise of legislative power depends on the way it "prescribes the regulatory structure" for agency decisions and the extent it "effectively directed the focus of the [agency's] discretionary judgement." Batterton v. Marshall, 648 F.2d at 706. The purpose of this analysis is to decide whether the agency exercised its delegated power to significantly affect

---

1. Public notice and comment "before a legislative rule becomes effective can reduce the risk of factual errors, arbitrary actions and unforeseen detrimental consequences." Chamber of Commerce v. OSHA, 636 F.2d at 470.

2. "Where the knowledge base for rules is uncertain, public confidence is possible only if the procedures followed promote full and open debate..." 628 F.2d at 621, n.93. Like the child pesticide rules in the Farmworkers case, the radioepidemiological tables are the first attempt by HHS to deal specifically with radiation compensation policy, and like them "the utmost care in [the rule's] development and exposure to public and expert criticism" is needed. 628 F.2d at 621.

the members of the public. If it has, then the agency action will not be considered the kind of action Congress undertook to exempt from APA requirements regulating the rulemaking process. Pickus v. U.S. Board of Parole, 507 F.2d 1107 (D.C.Cir. 1974).

III. Applicability of the APA Rulemaking Procedures to the HHS Risk Tables:

Utilizing this functional approach, we need then to determine both the intent and the effect of the tables in order to determine the applicability of APA rulemaking requirements. The intent behind development of the risk tables can be found in at least three expressions: that within the legislative history of P.L. 97-414, expressions of Health & Human Services itself as to its understanding of the use of these tables, and last fall's hearing before the Senate Labor and Human Resources Committee.

The broadest interpretation of the intended purpose to which these tables would be applied is that of the legislation's sponsor, Senator Hatch. The ultimate importance of the tables, he stated at the time of introduction of his bill, would be in "gaining a better understanding of the health effects of radioactive fallout from above-ground testing of nuclear weapons." (S.13223, Oct. 1, 1982) Senator Kennedy was more specific:

> For several years I have worked to enact legislation establishing a compensation system for American citizens exposed to radiation as a result of open air atomic bomb testing during the 1950's at the Nevada Test Site. One of the roadblock to our moving this important legislation is our lack of complete understanding of... the causal relationship between exposure to low level ionizing radiation and cancers. The proposed studies are intended to answer these questions. (Congressional Record, S.13225, Oct. 1, 1982)

HHS's intent in developing the risk tables is set forth by the committee impaneled to develop the tables. The Rall Committee notes in its final report Senator Hatch's intent, "to use as the basis for award of compensation the tables of probability of causation of cancer from radiation exposure, prepared in response to the requirements of the Orphan Drug Act." (Report of the N.I.H. Ad Hoc Working Group to Develop Radioepidemiological Tables, page 1). This intended purpose is reaffirmed by the National Research Council of the National Academy of Sciences, charged by HHS with oversight of the Rall Committee's work. In the preface to its report, the NRC states: "The objective in developing such tables of probability of causation was to provide the scientific basis for an eventual formula for compensating cancer victims who claimed that ionizing radiation was the source of their cancers." (Assigned Share for Radiation as a Cause of Cancer, also referred to as the "NRC Oversight Report"). In this same report, the NRC notes several categories of intended application for the tables once developed, and notes as well other conceivable applications. (NRC Oversight Report, pp. 10 & 11)

Any remaining doubt as to the intended applicability of these tables should be put to rest by reviewing the transcript of last fall's hearing before the Senate Committee on Labor and Human Resources addressing the draft tables. For example, in response to numberous issues raised about methodology, "probability of causation" vs. "assigned share", and applicability of the tables in different contexts, Senator Hatch stated: "What we hope the draft report, and finally the final report, will do is give us some basis, statistical or otherwise, upon which to base a resolution of these problems." ("Radiation Cancer Liability", Hearing before the Committee on Labor & Human Resources, 98th Congress, 2nd Session, September 18, 1984, at page 131)

Turning, then, to the second half of the test for applying APA rulemaking procedures, it is evident that the effect of these tables will be to significantly affect the rights of members of the public. Assuming Senator Hatch is successful in gaing passage of this proposed "Atmospheric Nuclear Testing Compensation Act," the most immediate effect will be upon the rights of fallout victims of the Southwestern region. Under this proposed legislation, the tribunal which would be created to review radiation claims and determine damage awards is specifically directed to, "use as a guide the most recent report published" by HHS pursuant to §7(b) of the Orphan Drug Act.

Even if passage of Senator Hatch's legislation does not occur, Senator Hatch himself has noted that the value and effect of these tables will be to, "catalogue for each radiogenic cancer the probability that a given dose of ionizing radiation caused the cancer of a victim who received such a dose." (Congressional Recrod, S.13223, Oct. 1, 1982) Such a catalogue of defined "probabilities of causation" could readily be incorporated into other judicial and administrative compensation schemes. The NRC Oversight Report did in fact note that, "Judicial or administrative interpretations could easily broaden the use of the tables." (NRC Report, at page 124) Certainly the 400 page decision in Allen v. USA evidences the degree to which the courts will investigate and incorporate any and all notions of causation in an effort, as Judge Jenkins couched it, "to formulate an ordered theory of decision." Use of these tables, notwithstanding further action by Congress, must be viewed as a serious and real prospect -- especially where many representatives of the scientific community have stressed that, "the only practicable method of linking radiation exposure to the later development of cancer is through the science of radioepidemiology." (Statement of Senator Hatch on the Congressional Record, S.13223, Oct. 1, 1982)

This attempt by other administrative bodies to incorporate the radiation risk tables into their decisionmaking with respect to radiation claims may, in fact, have already begun. Recently the Veterans Administration published proposed rules for the resolution of compensation claims brought by veterans who served in U.S. atmospheric nuclear weapons testing. Although these proposed rules do not specifically adopt the use of the HHS tables, the proposed rules do acknowledge that the V.A. is presently assessing "the potential utility of employing the tables in some fashion to adjudicate veterans' compensation claims." (Federal Register, Vol 50, #77, p. 15852, April 22, 1985)

In deed, the situation before this Committee with respect to the risk tables is not unlike that ruled illegal by Judge Greene in Gott v. Nimmo, an action which challenged the failure of the V.A. to follow the APA before using certain V.A. and Defense Department documents in assessing the validity of radiation claims. (U.S. District Court, District of Columbia, September 30, 1981) Of particular concern in that case was a "Memorandum of Understanding" between the V.A. and the Defense Department, the stated purpose of which was to "formalize and improve" the procedures for determining radiation exposure estimates for "atomic veterans." In essence, the "Memorandum" allowed the Defense Department to develop a methodology for determining radiation exposures at different atmospheric nuclear weapons tests and for assigning exposures to veterans claiming to have incurred a radiogenic disease as a result of their participation in those tests. In ruling that the APA applied, the district court upheld the plaintiffs' allegations that they were injured by the government's failure to conduct rulemaking on the "scientific and policy assumptions" that supported, among other things, the government's "radiation reconstruction efforts."

Ms. TUCKER. We have referred to a number of problems we had with the composition of the committee, and I would like to open by reemphasizing that. We are saying that the plaintiffs' experts and those who have publicly opposed Federal radiation standards have been excluded both from the panel developing the tables and from the oversight panel.

We also have some specific concerns with some of the committee members, and we raise these concerns in a background under which the Federal Government has a rather poor record in letting the public know about radiation health problems. Senator Hatch has already referred to some of this background in the case of people living downwind of the Nevada atomic test site where the Federal Government, instead of properly warning citizens, urged them to go out and watch atomic detonations where they were more exposed to the dangers of atomic fallout.

In the spring of 1953, the Federal Government went even further and claimed that sheep killed by especially dirty atomic tests had not been damaged by atomic fallout. Congressional hearings held in 1979 revealed that the Federal Government engaged in a concerted effort to disregard and to discount all evidence of a causal relationship between exposure of the sheep to radioactive fallout and their deaths. The evidence was so strong that District Judge A. Sherman Christensen, who had originally denied compensation to the sheep ranchers in Federal court, ruled that a fraud had been perpetrated upon the court, and reopened the case in August of 1982. Two of the researchers involved in the sheep case fraud upon the court were later placed in charge of studies into the radiation health effects on nuclear workers at Department of Energy facilities.

Frankly, if a researcher has engaged in a fraud upon the court on behalf of the Federal Government involving radiation before, I do not place a great deal of confidence in any future studies that he might do related to radiation health effects.

Yesterday, Senator Metzenbaum referred to Dr. John Gofman being drummed out of Federal employment after challenging Federal radiation exposure standards. I believe that the witness, Mr. Robert Alvarez, also referred to the work of Dr. Thomas Mancuso who, in studying Federal radiation workers, refused to sign a press release claiming there was no cancer increase at the Hanford site in Washington State. When Dr. Mancuso refused, his contract officer, Dr. Sidney Marks, initiated the paperwork to prevent authorization of future research funds. Dr. Marks then left the Atomic Energy Commission to take over the Mancuso study. Dr. Marks was one of those scientists involved in the fraud upon the court in the Utah sheep case.

Later congressional hearings revealed that Dr. Mancuso had received favorable peer reviews suggesting that his work should be expanded, not canceled, except for the peer review by Dr. Marks. Before all funds could be terminated, Dr. Mancuso enlisted the aid of renowned epidemiologist, Dr. Alice Stewart and her statistician, George Kneale. They published a paper indicating increased risks of bone marrow cancer, pancreatic cancer, and lung cancer for workers who received allowable doses under Federal standards of exposure. The Atomic Energy Commission successor agencies tried to confiscate Dr. Mancuso's data base and then circulated substantially less complete data to other researchers seeking to refute the Mancuso findings.

Dr. Irwin Bross of Roswell Memorial Institute was studying potential radiation damage from medical procedures in the tristate survey. He criticized the use of mammographies, warning that their high exposures would cause more cancers than they cured. A peer review committee of radiologists who were giving the mammographies to women urged an end to his funding even though they lacked credentials as epidemiologists. Dr. Bross' challenge to Federal radiation standards resulted in an end to his Federal funding.

The funding cancellations for Dr. Bross and Dr. Mancuso were addressed in the 1978 hearings by Congress, and the underlying political motivations are laid out in those hearings.

Because of these examples, it would not be surprising if federally funded researchers felt that challenges to Federal radiation standards might result in economic reprisals, to them or to their institutions. That is why we think it is so important that people who have been willing to raise concerns about radiation risks should be included on these Federal panels such as the Rall panel.

The Rall panel, or the Ad Hoc Committee to Develop Radioepidemiological Tables, was challenged by radiation victims because of its composition soon after they learned about the panel. As Mr. Brown pointed out, the panel contained three scientists who testified against radiation victims, but none who testified on behalf of them.

However, we particularly oppose the inclusion of Seymour Jablon, because he coordinated a study of atomic veterans who were early entrants to Hiroshima and Nagasaki. This study, when reviewed by the Office of Technology Assessment, was found not to support any conclusions, the study was set up in such a way that even if there were a cancer increase, it would not appear in the study itself. The study was undertaken in a way that someone like myself, who has just taken a basic epidemiology course, could spot the problems with the study.

A reasonable person might easily conclude that the Jablon study was lying and cheating. A reasonable person might conclude that they could not trust Jablon to provide honest answers about radiation health damage to atomic soldiers or others. Is it any wonder that radiation victims' groups do not trust the findings of this committee when it contains people that have falsified studies in the past, when it contains people who have testified against them in court, but did not contain people that could provide an opposing viewpoint?

Dr. Rosalyn Yalow was appointed to replace a panel member suffering from poor health. She has made such biased and inaccurate statements as, "There is absolutely no evidence that low levels of radiation are harmful to human health," and "Low level radiation is safe," despite universal agreement among reputable scientists that there is no safe level of ionizing radiation. Dr. Yalow even went so far as to suggest that Utah citizens "are the healthiest in the Nation, and if anything, it seems as if the radiation is good for you." Clearly, she has a very biased viewpoint.

Scientists who have denied radiation dangers or sanctioned improper studies to hide these effects have no place on panels trying to develop objective estimates of radiation risk. We have been told that, well, even though there were some conflicts of interest within the panel, there was a National Academy of Sciences Oversight Panel. Once again, three members of the panel have testified on behalf of the Government or the defendant in radiation claims, while none of the experts testifying on behalf of radiation victims were included.

Dr. Eugene Saenger's name on this NAS panel raised such concerns that I doubt that many people will place much credence in its findings. In 1978 congressional hearings, Congressman Doug Walgren stated,

> Dr. Saenger's experiments read like something out of Frankenstein. There is no getting around that. The relationship between Dr. Saenger and the Department of Defense seems quite clear, at least to great parts of the public who have to rely on the results of your study.

Congressman Walgren was referring to Department of Defense financed studies conducted by Dr. Eugene Saenger at the University of Cincinnati in which cancer patients were exposed to total body irradiation to gather data on how soldiers might fare on the nuclear battlefield. The subjects were 87 cancer victims who were poor—84 out of 87 were charity patients; who were mostly black—61 out of 87 were black; and they had little education—their mean education was 5 years. Most of the patients were clinically stable, and many of them were working daily, but after whole-body irradiation treatment of up to 250 rads, 25 out of 87 patients died within 60 days. At this time, scientists employed by the Federal Government to do contract research were warning the Government that doses of 250 to 300 rads were likely to kill half of the patients so exposed. However, they did not tell the patients that this high probability of death was going to result.

Through the years of this experiment there were no indications of therapeutic value in reports filed with the Pentagon, and the Junior Faculty Review Committee of the University of Cincinnati could find no evidence of therapeutic value. Although patients were told that their radiation exposures would help their sickness, the Junior Faculty Association of the University of Cincinnati condemned the experiment, saying,

> We have come to the conclusion that many patients in this project paid severely for their participation, and often not knowing that they were part of the experiment. We feel that the evidence clearly calls into question the manner in which these human experiments were designed and carried out.

This is not the kind of person that I will trust to give me an accurate evaluation of radiation exposure risks.

Senator SIMPSON. Ms. Tucker, I do not want to be rude, and I am not a rude person, but I would like to hear all the testimony I could and also be able to respond with questions, and I am going to be pressed to do that.

Ms. TUCKER. I would like to point out that there are six representatives of defendants in radiation litigation cases appearing here today; only three who represent the interests of people exposed to ionizing radiation. I do not think that is really a balanced panel.

So I am going to press on and try and bring my views to you orally, to make sure that they have been heard.

Senator SIMPSON. Well, they will be heard, but they would better be heard by a live human being up here, and the only way we are going to do that is to move on.

I wanted to be sure that I was here so that your view could be expressed, because I know that you had problems with the composition of the group. I am well aware of that.

So, let me ask some questions now, if I may.

Ms. TUCKER. May I first give you our four recommendations for action, on page 11 of our testimony?

Senator SIMPSON. You may indeed, if you can summarize that very swiftly.

Ms. TUCKER. No. 1, the Office of Technology Assessment should be asked to investigate the process by which the ad hoc committee members were selected, and to advise this Senate committee about the issues and concerns that have been raised about the present tables.

No. 2, the tables and methodology developed by the ad hoc working group for Health and Human Services should be submitted to public comment by publication in the Federal Register for review pursuant to the requirements of the Administrative Procedures Act. We have attached a memo regarding our view that the Administrative Procedures Act applies.

No. 3, an additional half-day of hearings should be held before the Senate committee to begin redressing the favoritism shown to radiation defendants by allowing radiation victims and independent scientists an equal opportunity to be heard and to assist this committee with their expertise and concerns.

We have been told that radiation victims could not appear because they were not scientists, yet we have the attorneys representing the nuclear industry and others appearing on behalf of the defendants. We think that the victims have just as much right to be heard on this issue.

No. 4, a more balanced panel should be appointed after deficiencies in the process have been identified, such as by the OTA review and by these committee hearings, and after consultation with all interested and concerned parties. In the meantime, the tables should be placed on the shelf, with it being made explicitly clear by this committee that the tables and the report are not to be used before any tribunal adjudicating radiation cancer claims, until we have addressed such things as reevalulating the actual doses to A-bomb survivors and so forth.

Senator SIMPSON. Thank you. I appreciate your testimony. It is very helpful to us. Senator Hatch has been through the entire process of the hearings, before and after, and I think there has been a clear distinction between trying to obtain scientific evidence and that which is not scientific and which is often very painful and very humanly compelling. So we know that, we are well aware of that.

Let me ask you now, if I could, Mr. Brown, as I understand your position, you object to these probability of causation tables because the panel that assembled the tables was unfairly biased in the direction of the viewpoint that radiation risks are less significant than you or the organizations that you represent have personally concluded.

If the group that prepared these tables were to have included the representitives from the independent scientific community that you have suggested, would you then support the probability of causation approach as a means of compensating radiogenic cancer claimants?

Ms. TUCKER. Dr. Rosalie Bertell has prepared a set of tables which give different risk estimates as the basis for it and demonstrate that there is a wide range of views, and that by using another formula, you would come up with different probabilities depending on which original estimates you decide to use.

I think that if we had both sides appearing and working together on such tables, that they probably would end up by saying, "Well, the risk ranges from here to here," and then would give some indication to the factfinder about why there are arguments for a low range and why there are arguments for a high range.

In reviewing the footnotes within the report, I note that many of the most recent studies which look at human data in groups exposed to what are regarded as low doses of radiation, so many of the most recent studies were excluded. Now, in some of these studies, they did not have accurate dosimetry because people living near facilities did not know that they were in danger. But I think if our scientists had been present, that these studies would have been brought forward and debated and brought into the deliberations.

Senator SIMPSON. Let me ask you this. As I understand the logic of the probability of causation approach to compensating individuals exposed to radiation, wouldn't it be possible if we endorsed this approach for an individual, say, with 30 percent probability of causation that his cancer was caused by radiation, to recover 30 percent of a full award and then later bring a lawsuit alleging that his cancer was the result of, say, benzene exposure, and if he could then demonstrate a 50 percent or greater likelihood of that, thereby meeting the normal tort standard in ordinary litigation, then recover a full award for the benzene exposure. Have we not, then, compensated that individual for approximately or actually 130 percent of his claim?

Mr. BROWN. Actually, Senator, I would take it a little bit beyond that. First, I might add that again, it ultimately depends on the tables that are being applied and also the validity of the dose evidence that you have. But one of the concerns I have with the approach that is being proposed by Senator Hatch, and he had actually asked me about this, was with the compensation proposal that he is considering adding to the compact free association is this exclusivity of remedy situation, because what I am afraid of is that, as Dr. Johnson pointed out yesterday, there are a number of radiation—related cancers that have not been addressed in the risk takes. What happens if you have an exclusive remedy set up, and the plaintiff, having one of these other cancers, simply cannot find justice because these tables do not address it, I believe he should be allowed to go into the court system to try and prove those types of cases to the best of his ability.

Also—and I am sure this would gather some heat somewhere—I would say that if a fair and equitable strict liability compensation scheme was set up, and you had something like this 30 percent PC that was established, and the victims then felt that they could establish in Federal court by a preponderance of the evidence proof of a relationship—on radiation; forget about the benzene and the other carcinogens he may have been exposed to—that he should be allowed to try to recover that additional 20 percent in the Federal court through the Federal tort system.

Senator SIMPSON. Well, that is an interesting thought. Let me ask you this. If one is to accept this premise based upon our current scientific knowledge, that it is next to impossible to prove that a given cancer was or was not caused by an earlier dose of radiation, how do you respond to the claim that under our current tort law approach to these cases, a claimant will either be undercompensated or overcompensated, depending upon where the trial judge decides to impose the burden of proof; how do you respond to that?

Mr. BROWN. Well, certainly, we have problems when you are trying to develop clinical proof of a relationship between exposure and evidence of a disease that arises 20 years later. But I think that to some extent, Judge Finesilver in the *Allen* decision did a remarkable job of applying existing epidemiological data and current and well-accepted principles of tort law in arriving at a fair and equitable decision. And I might suggest to the committee that they take a look at what I believe is an excellent article in Fordham Law Review, volume 52——

Senator SIMPSON. I will be glad to accept that into the record.

Mr. BROWN [continuing]. Because I do believe that this helps address some of the present problems that we are having with the process at this point in time.

Senator SIMPSON. Well, my thought, having practiced out there in the weeds for 18 years, is that the problem of mixing the PC approach with the traditional tort standard approach might well result in overcompensation, since tort law fully compensates for all claims over 50 percent. That is going to be an interesting issue in this.

A final question. You wrote me a letter which was rather detailed—do you remember that?

Mr. BROWN. Yes.

Senator SIMPSON. I remember that. You raised a number of questions about assumptions and data that went into developing probability of causation tables, arguing that those assumptions underestimate the risk of radiation. Along that line, then, I have three questions within this.

Based upon the most recent data, how many cancers occur in the United States of America from all causes annually? That is No. 1. And, of this total number, how many are related to radiation exposure? That is No. 2. And, of those related to radiation exposure, how many are as a result of natural background exposure, and how many are related to weapons testing and fallout?

Mr. BROWN. I am hoping——

Ms. TUCKER. Well, Senator, that is the subject of——

Senator SIMPSON. One at a time, please.

Ms. **Tucker**. That is the subject of this whole debate about radiation risks, and that is what the experts disagree about.

Senator **Simpson**. Well, they did not in 1981. They gave me a table here as to what that was. I would like to know what it is currently.

Ms **Tucker**. The Rall committee gave you their estimate of that. We would be happy to request answers to your questions from our scientific advisors and submit them for the record.

Senator **Simpson**. You do not have that information available right now?

Mr. **Brown**. It is not really our area of expertise.

Senator **Simpson**. I would think it would be very much your interest to know what that is.

Ms. **Tucker**. Senator Simpson, that is the subject of debate before the courts. What happens is that the defendants' witnesses——

Senator **Simpson**. I do not believe that that could be——

Ms. **Tucker** [continuing]. Who are represented on that committee have been coming forth with their answers. There is no central national cancer registry that can record the number of cancers and their causes.

Senator **Simpson**. I see. Well, I think it was just an idea of mine; it might be a good idea. I just thought if we knew how many cancers there were in the United States of America this year, how many were directly attributed to radiation, how many were directly attributed to fallout—and we have had those kinds of figures for more than several years; the latest one I have here, I believe, is 1980, which discloses that there was known, total, all cancers, 400,000, and that the total from all radiation sources was 6,007——

Ms. **Tucker**. Someone attributed those to radiation, Senator, but those cancers did not come——

Senator **Simpson**. Just let me finish, please.

Ms. **Tucker** [continuing]. With a diagnostic tag saying, "Caused by ionizing radiation."

Senator **Simpson**. Well, I do not want to be trashed here, but I would like to finish; 6,007 cancers attributed to all radiation sources. Of those 6,007: 3,050 from natural background radiation; 2,600 from medical diagnostics; 150 technologically enhanced; and 200 from development and fallout, which is five ten-thousandths of the cancers in that year in the United States.

So, if you will please furnish me the information for this year, I would greatly appreciate that and enter it into the record, unless you have something to add.

Ms. **Tucker**. Senator, the figures that have been furnished to you, attributing various cancers to different sources, are based on conjecture. They are educated guesses. They are based upon——

Senator **Simpson**. I think there is a lot of that going on in here, so I would not want to miss anybody getting a chance to do that. I mean, let's not deny that remarkable opportunity of everyone.

Ms. **Tucker**. The fact that somebody wrote down a number does not make it true.

Senator **Simpson**. I do believe you, my dear, and I really promise you, I do—including your figures. So, why go on? In this place, if you do not like the figures you get from CBO, go and get them from OMB; if you do not like those, get them from GAO. I know how that game goes. We play that with orchestra music here.

Yes?

Mr. BROWN. Yes; I believe there is somebody in the room here that perhaps could shed some light and help illuminate this particular question, if you——

Senator SIMPSON. If you will just submit it into the record, and I do appreciate your testimony very much. You have access to my staff and to me, if you wish to share anything further, and I appreciate very much your appearing here today.

We will go on now to panel No. 3.

Mr. BROWN. Senator?

Senator SIMPSON. Yes?

Mr. BROWN. I hesitatingly ask if you could bear with me for 2 minutes, just to point out a couple——

Senator SIMPSON. You know, I have been very generous, and I would rather have someone here to hear the testimony, and the only way that will happen is if I go on. So, furnish it to me for the record, call me on the phone; I will be there. You will find me accessible.

Mr. BROWN. I will put it in writing.

Senator SIMPSON. Thank you.

That is the conclusion of this panel.

Now we will have Mr. Robert Catlin, Electric Power Research Institute of Palo Alto, CA, and Dr. Ralph E. Lapp, consultant, from Alexandria, VA, please.

And if I may, I want to emphasize that I would hope you would conclude your remarks within the 5-minute limit as expressed in the original invitation. I hate to do that, but I certainly do not want you testifying before staff or a vacant chair, and I am going to try to stay here until we get that done.

So, Mr. Catlin, please.

STATEMENT OF ROBERT CATLIN, ELECTRIC POWER RESEARCH INSTITUTE, PALO ALTO, CA, AND DR. RALPH E. LAPP, CONSULTANT, ALEXANDRIA, VA

Mr. CATLIN. Good morning.

Senator SIMPSON. Good morning, sir.

Mr. CATLIN. Senator Simpson, my name is Robert Catlin, and I am a scientific adviser in the Energy Studies Center of the Electric Power Research Institute, located in Palo Alto, CA.

I would like to express my appreciation to the members of this distinguished committee for the invitation to present testimony today.

Although I work for EPRI, a private nonprofit corporation established by the power industry to conduct research to improve the generation of electric power, the opinions expressed here are my own, and are not necessarily those of EPRI or the power industry.

With your permission, I am going to condense my remarks, and I would like to submit, then, the typed copy for the record.

Senator SIMPSON. I would deeply appreciate that. Thank you.

Mr. CATLIN. The methodology developed by the NIH working group is based on population statistics for a general population of both sexes and specified age levels. In my testimony, I will direct attention to the workers in the nuclear industry who are generally male and whose age at initial exposure of radiation is usually 20 or more. The typical average annual exposure for such workers is on the order of 1 rem, and the typical exposure lifetime is on the order of 10 to 15 years.

In the first chart, on my left and your right, is a comparison of the developmental bases which have been used for two purposes—for the development of radiation protection standards and for the probability of causation. I put these up to illustrate both the similarities and the differences between them.

Radiation protection standards have been based largely on risk analyses performed by the BEIR committee, and they apply generally to all cancer sites as shown and all age groups. They are what I would consider conservative and therefore represent an upper-bound estimate of risk approach.

For probability of causation, an attempt was made by the NIH working group, it seems, to develop a best estimate of type of risk estimate, which would appear to be demanded by the courts. There are some distinctions here—that is, chemical carcinogens and smoking are recognized as potential risk contributors. They do not exist, or have not really been applied in basic radiation protection standards. There is provision for including the risks from medical diagnostic and therapeutic procedures. The cancer sites are somewhat more limited, as are the age groups, depending on the available epidemiological information.

The next chart illustrates further comparison of the developmental bases, and we see again the provisions for radiation protection standards that have been based largely on BEIR estimates. On the right, it shows the changes made by the NIH working group, in order to obtain a best or a better estimate of the risk.

This next chart is an illustration of a situation where I took a worker who was exposed one time to a 5-rem dose at age 20, of which 50 percent of the dose went to bone marrow; it compares the absolute risk model in red, the model used for the radiation protection standards, with the relative risk model, wave function, derived by the NIH working group, and shows how the pattern of retrospective risk, or probability of causation for leukemia distributes over time.

In the upper-bound estimate, a maximum probability of causation of 26 percent is estimated. This drops to approximately 14 percent under the relative risk model at age about 25.

This next chart illustrates another consideration taken into account by the NIH working group: That is the emphasis on smoking being counted as a contributing risk. Here, we see the probability of causation for lung cancer which is associated again with a single-time, 5-rem dose at age 20. The solid red line represents the average individual in the population, combined smoking and nonsmoking; the top blue line, nonsmokers; the red dotted line, former smokers, and the bottom blue line, an average smoker. The maximum probability of causation, then, for this single radiation exposure case drops from the nonsmoker at about 4.3 percent to about 0.4 percent for the smoker, a range of 10. If we looked at the heavy smoker, it would go down even further.

Now, the examples in my prepared testimony discuss, in effect, what has happened with regard to these single exposures. In this next particular chart, I am presenting the case of thyroid cancer, the situation where an individual is exposed to the maximum average dose permitted under the standards—that is, 5 rems per year to the whole body, 50 percent of which goes to thyroid. And we see for exposure periods of 15 years, how the probability of causation changes with a delay of start of exposure, according to the start of employment, as a radiation worker.

I should note that this example represents an extreme case, showing a high of 35 percent probability of causation; for a worker who is exposed to the U.S. average of about 1 rem per year, this would drop to approximately 5 percent.

Senator SIMPSON. Again——

Mr. CATLIN. All right. I am coming to my conclusion, Senator.

Senator SIMPSON. Thank you very much.

Mr. CATLIN. I do want to make one point, however, before the conclusion, a very short point. The final and highly important issue is one raised by the working group itself, namely, the extrapolation of positive dose-response relationships below the level of 10 rads. This is an action that was declined by the BEIR committee, for which there is continuing supporting evidence from the latest Hiroshima and Nagasaki studies. Such an extrapolation is understandable for radiation protection purposes, making an extrapolation like this for estimates of causation, possibly leading to liability and compensation decisions appears unjustified and warrants further examination.

I would then like to present the following conclusions.

First, the NIH report presents a methodology that is complex, not simple, for addressing questions of cancer causation from exposure to various sources of risk, particularly radiation exposure.

Second, the NIH working group has developed methods for evaluating prospective risk that are more advanced than any previously available. Such methods appear to be applicable equally to the setting of radiation protection standards and for retrospective estimates of cancer causation.

Third, the new risk assessment methods are in some ways broader and in other ways more narrow than present methods used for setting radiation protection standards. More scientific evaluation of NIH working group methodology is needed to determine the adequacy and utility of these methods.

Fourth, as it now stands, the NIH report appears best-suited for use as guidance. It does not contain sufficient information for use directly in establishing compensation practices or procedures.

Fifth, another committee should be established, perhaps, to consider frameworks for application of this methodology. Such a committee should at least include knowledgeable representatives from the scientific and technical community, the legal community, agencies involved in compensation determinations, industry, labor, the public, and the insurance industry.

And last, provided the NIH report methodology stands the test of further scientific scrutiny, the risk assessment processes set forth therein would appear to make previous determinations of causation suspect, particularly where such determinations were based on conservative health protection philosophies and procedures.

Senator SIMPSON. Thank you very much, Mr. Catlin.

[The prepared statement of Mr. Catlin and responses to questions submitted by Senator Hatch and Simpson follow:]

STATEMENT BY
ROBERT J. CATLIN
BEFORE THE
JOINT HEARINGS OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
AND THE
SUBCOMMITTEE ON NUCLEAR REGULATION OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
JUNE 12, 1985

Mr. Chairman and Subcommittee members, my name is Robert J. Catlin. I am a Scientific Advisor in the Energy Study Center of the Electric Power Research Institute (EPRI), located in Palo Alto, California. I would like to express my appreciation to the members of this distinguished Committee for the invitation to present testimony today. Although I work for EPRI, a private non-profit corporation established by the power industry to conduct research to improve the generation of electric power, the opinions expressed here are my own and are not necessarily those of EPRI or of the power industry.

INTRODUCTION

The probability of causation methodology and related radioepidemiological tables prepared by the National Institutes of Health *ad hoc* Working Group to Develop Radioepidemiological Tables (NIHWG) were published as a report by the U.S. Department of Health and Human Services on January 4, 1985. For simplicity, this publication will be referred to as the "NIH Report"[1] in this testimony. The methodology and related tables represent a major departure from the classical conservative radiological risk assessment practices presently applied to the setting of health protection standards. The most significant change is the use of "best estimate" risk assessment approaches for application to estimates of causation that may prove of use in liability/compensation decisions. On the other hand, conservative "upper bound" risk assessment methods have been used for establishment of radiation protection standards; prior to the release of the NIH Report, such methods have been the only ones available for causation determinations. It is most appropriate that conservative risk estimates be used for health protection purposes; it is equally important that "best estimate" approaches be used to examine risk and likelihood of causation for compensation purposes.

In a comparison of risk assessment results, those derived from "best estimate" approaches using the NIHWG methodology generally lie well below those obtained from radiation protection practices, as derived from the BEIR Report (1980)^{2}, illustrating the conservative nature of the radiation protection standards. However, should the opposite situation prevail, the degree of conservatism would be suspect, and re-evaluation of the radiation protection standards would be warranted.

The methodology developed by the NIHWG is based on population statistics for a general population of both sexes and specified age levels. In this testimony, attention is directed to workers in the nuclear industry who are generally male and whose age at initial exposure to radiation is usually 20 or more. The typical average annual exposure for such workers is on the order of 1 rem, and the typical exposure lifetime is on the order of 10 to 15 years in duration.

CHANGES IN DEVELOPMENTAL BASES

A comparison of the developmental bases for deriving radiation protection standards, on the one hand, and probability of causation per NIHWG methodologies, on the other, shows some significant differences, as given in Figure 1. Most significant in the probability of causation methods are the provisions for including consideration of smoking and exposures to other non-radioactive sources of risk, radiation exposures from medical procedures, and risk relationships that are multiplicative in nature.

A similar comparison of the developmental bases for modeling is given in Figure 2. The practice has been to use absolute risk projection models, coupled with linear dose-response models, as given in the BEIR Report (1980)[2], to achieve conservative "upper bound"estimates of risk for use in setting radiation protection standards. Instead, the NIHWG chose to use a relative risk projection model, coupled with linear or linear-quadratic dose-response models as appropriate, to more closely fit the risk assessment values to the updated epidemiological data now available. Even though the NIH Report presents the risk projection model for leukemia and for bone cancer in a relative risk "wave function" form, for these sites the models have in reality been transformed from an absolute risk projection model, as correctly identified in Figure 2.

To illustrate this tranposition further, consider a male worker who receives a whole body exposure of 5 rems of low-LET radiation at age 20, and who subsequently develops leukemia. The probability of causation for various ages at diagnosis will depend heavily on the modeling used, as shown in Figure 3. Using an absolute risk projection model (ARM) with a linear dose-response model (as used in radiation protection determinations), a peak probability of causation level of 26% is estimated, should his leukemia be diagnosed at ages 23 to 25. The box-like appearance of the curve results from the 5-year groupings for baseline leukemia incidence in the U.S. male population, as given in the SEER data.[3] The truncated appearance of the curve is due to a 25 year risk expression period specified in the BEIR Report (1980)[2] on the basis of the epidemiological data then available, hence, the cutoff of risk at age 46.

In contrast, the relative risk "wave function" model (RRM) given by the NIHWG and coupled with a linear-quadratic dose-response model (LQ) results in a similar probability of causation distribution, but with a lower peak level of about 14% at age 25. The relative smoothness of this curve is likely due to a more precise determination of annual leukemia baseline incidence from SEER data[3], and the extension of the risk expression period from 25 to 49 years after exposure, based on improved and extended epidemiological data. The baseline incidence for the two curves is essentially identical: thus, the curves give a graphic illustration of the difference between "upper bound" (top curve) and "best estimate" (lower curve) determinations. The absolute risk projection model nature of the NIHWG's "relative risk" model is confirmed not only by the shape of the lower curve in Figure 3, but also by the fact that age of exposure and age at diagnosis must both be entered into the annual exposure calculus.

A similar circumstance exists in the NIHWG methodology for cancer of the bones and joints. The important point is that use of the absolute risk projection model in lieu of the modified "relative risk" model would facilitate the computation of probability of causation in circumstances where more than one source of carcinogenic risk had to be taken into account, particularly for a cancer as important as leukemia. Moreover, adjustments in baseline incidence levels and other refinements would be facilitated.

As a case in point, determination of the probability of causation for lung cancer under identical exposure conditions may illustrate the difference between models, as shown in Figure 4. Using the absolute risk projection models and linear dose-response models, as given in the BEIR Report (1980)[2], the probability of causation values (upper curve) follow a typical log-normal, skewed left distribution, with a peak of about 13% at ages at diagnosis of 37 to 40. On the other hand, the relative risk projection model (lower curve) reaches a plateau of about 0.6% probability of causation 10 years after the year of exposure. For this model, the linear-quadratic model was used. This plateau is typical of relative risk projection model determinations.

ADJUSTMENT FOR SMOKING HISTORY

In setting radiation protection standards for the lung, no adjustments have generally been made for cigarette smoking history. Thus, the probability of causation values in Figure 4 represent the average mix of smokers and non-smokers in the U.S. population. The NIHWG recognized the necessity of making adjustments for individual smoking practices because of the substantial risk conveyed by the smoking when compared to the substantially lower contributions from radiation exposure. Such adjustments are provided in the NIH Report.

To illustrate the adjustment process, consider a male worker exposed to a whole body dose of 5 rems low-LET radiation at age 20, who subsequently develops lung cancer. His probability of causation of various degrees of cigarette smoking history is presented in Figure 5. Following NIHWG methods, a linear-quadratic dose-response model is used. Again, the typical plateau curves associated with the relative risk projection model appear. As a non-smoker, the worker would reach a plateau of about 4.2% at age at diagnosis of 30 and beyond. If he were a former smoker, the plateau would drop to about 1%. As an average member of the U.S. population, the plateau would drop still further to about 0.6%, reaching a low value of about 0.4% for an average cigarette smoker. For a heavy smoker, the plateau would drop still further.

This NIHWG methodology is both innovative and informative, and represents a major contribution to the understanding of the relative contributions to causation of lung cancer from cigarette smoking and from radiation exposure.

INFLUENCE OF OTHER FACTORS

All of the previous examples have considered situations involving radiation exposure in a single year. Such situations are uncommon for radiation workers, and were introduced for illustrative purposes. Consider an average non-smoking male worker exposed to an average annual radiation dose of 1 rem, low-LET radiation, for an exposure working lifetime of 15 years. In this case, his lifetime dose would be 15 rems, of which 50% is assumed to be absorbed in lung tissue. Let his 15 year exposure experience begin at the various ages of 20, 25, 30 and 35 years, and that lung cancer is diagnosed but not before the initial year of exposure. The level of the probability of causation plateau will vary inversely with the starting age, as shown in Figure 6, ranging from 5% at starting age of 20, to about 2% at starting age of 35.

Taking an identical set of exposure circumstances, but considering thyroid cancer as the health effect of interest, similar curves may be derived, with two important differences, as shown in Figure 7. First, the relative plateau levels for probability of causation are much higher, reaching, for example, 14% for a worker beginning exposure at age 20. Second, the plateau levels for workers beginning exposure at ages 25 and 30 are essentially identical and not separated, due to shifts in the baseline incidence levels for thyroid cancer.

A substantial number of workers are exposed to radiation levels greater than 1 rem per year, however. The possible impact of higher annual exposure levels was evaluated by duplication of the exposure situations used for Figure 7, but with the average annual dose raised to 5 rems. The results, given in Figure 8, show substantial increases in probability of causation plateau levels for thyroid cancer, to a peak value of about 36% for workers beginning exposure at age 20. From a health protection standpoint, this level should not be alarming because a 5 rem whole body dose gives a prospective risk of developing thyroid cancer of about 6 chances in 1 million. It does illustrate some of the complexities that would affect decisions on how to utilize the NIHWG methodology in future applications.

Other factors affecting probability of causation determinations need further analysis, such as exposures of workers to high-LET radiation, or the admixture of exposures from medical procedures with exposures from industrial sources. Although the uncertainty analyses in the NIH Report[1] do not appear to raise insurmountable problems, these analyses have not been examined with technical rigidity. Another concern is the question of including primary sites of dubious radiosensitivity such as the pancreas.

A final and highly important issue is one raised by the NIHWG itself, namely the extrapolation of positive dose-response relationships below the level of 10 rads, an action declined by the

BEIR Committee, and for which there is significant evidence to the contrary from the latest Life Span Study Report[4] (Hiroshima-Nagasaki). Such an extrapolation is understandable for radiation protection purposes; making such an extrapolation for estimates of causation possibly leading to liability/compensation decisions appears unjustified and warrants further examination.

CONCLUSIONS

From a review of the NIH Report and the above analyses, the following conclusions have been reached:

1. The NIH Report presents a methodology that is complex, not simple, for addressing questions of cancer causation from exposure to various sources of risk, particularly radiation exposure.

2. The NIHWG has also developed methods for evaluating prospective risk that are more advanced that any previously available. Such methods appear to be applicable equally to the setting of radiation protection standards and to retrospective estimates of cancer causation.

3. The new risk assessment methods are in some ways broader, and in other ways, more narrow than present methods used for setting radiation protection standards. More scientific evaluation of the NIHWG methodology is needed to determine the adequacy and utility of these methods.

4. As it now stands, the NIH Report appears best suited for use as guidance. It does not contain sufficient information for use in establishing compensation practices or procedures.

5. Another committee should be established, perhaps, to consider frameworks for application of the NIHWG methodology. Such a committee should include, at least, knowledgeable representatives from the scientific and technical community, the legal community, agencies involved in compensation determinations, industry, labor and the public.

6. Provided that the NIH Report methodology stands the test of further scientific scrutiny, the risk assessment processes set forth therein would appear to make previous determinations of causation suspect, particularly where such determinations were based on conservative health protection philosophies and procedures.

Finally, this effort to employ retrospective risk analysis, be it called probability of caustion or by any other name, to increase the scientific validity of the determination of causation in cases of possible environmental illness is one to be encouraged. In my opinion, determinations of causation based on "expert medical opinion" have generally resulted in highly inconsistent and unpredictable decisions, resulting in what one individual has termed a "crap shoot". The very nature of scientific evidence is probabilistic, and we should not fear to introduce and to use such approaches where required.

REFERENCES

1. National Institutes of Health, Report of the National Institutes of Health ad hoc Working Group to Develop Radioepidemiological Tables, NIH Publication No. 85-2748, January 4, 1985, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Washington, D.C.

2. National Research Council, The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1981, National Academy of Sciences/National Research Council, Washington, D.C. (1980) (BEIR Report).

3. John L. Young, Jr., et al (Editors), Surveillance, Epidemiology, and End Results: Cancer Incidence and Mortality in the United States, 1973-77, NIH Publication No. 81-2330, National Cancer Institute Monograph No. 57, (June 1981) U.S.Sup't of Doc., Washington, D.C.

4. Life Span Study Report 9, 1950-78, Supplementary Tables, Radiation Effects Research Foundation.

FIG.1 **COMPARISON OF DEVELOPMENTAL BASES - GENERAL**

CONSIDERATION	RADIATION PROTECTION STANDARDS	PROBABILITY OF CAUSATION
o RADIATION RISKS	SOMATIC AND GENETIC STOCHASTIC AND NON-STOCHASTIC	SOMATIC STOCHASTIC
o OTHER RISKS	NONE	CHEMICAL CARCINOGENS AND SMOKING (WITH KNOWN DOSE-EFFECT RELATIONSHIPS)
o RISK RELATIONSHIPS	ADDITIVE	ADDITIVE AND MULTIPLICATIVE
o RADIATION SOURCES	INDUSTRY AND DEFENSE - OCCUPATIONAL AND PUBLIC EXPOSURES	INDUSTRY, DEFENSE AND MEDICAL PROCEDURES EXPOSURES
o PRIMARY CANCER SITES	ALL SITES (EXCEPT CHRONIC LYMPHOCYTIC LEUKEMIA)	12 SPECIFIED SITES - 14 SITES EXCLUDED
o AGE GROUPS	ALL AGE GROUPS	AGE GROUPS LIMITED FOR 7 OF THE 12 SPECIFIED SITES
o END POINT(S) OF INTEREST	MORBIDITY AND MORTALITY	MORBIDITY

FIG.2 COMPARISON OF DEVELOPMENTAL BASES - MODELING

CONSIDERATION	RADIATION PROTECTION STANDARDS	PROBABILITY OF CAUSATION
o RISK PROJECTION MODEL (OVER TIME)	ABSOLUTE RISK PROJECTION MODEL: ALL SITES	ABS. RISK PROJ. MODEL (WAVE FUNCTION): LEUKEMIA AND BONE CANCER RELATIVE RISK PROJ. MODEL: SOLID TUMORS EXCEPT BONE
o DOSE-RESPONSE MODEL	LINEAR: LOW- OR HIGH-LET: ALL SITES	LINEAR-QUADRATIC: LOW-LET: ALL SITES EXCEPT BREAST AND THYROID. LINEAR: LOW-LET: BREAST AND THYROID; HIGH-LET: ALL SITES
o RISK COEFFICIENTS	LINEAR (BEIR REPORT, 1980)	LINEAR ADAPTED TO LINEAR-QUADRATIC: SOLID TUMORS EXCEPT BREAST AND THYROID. LINEAR: BREAST AND THYROID
o LATENT PERIOD	BEIR REPORT (1980) VALUES	2 YEAR MINIMUM FOR LEUKEMIA AND BONE CANCER; SMOOTHED 5-10 YEARS FOR SOLID TUMORS

FIG.3 LEUKEMIA — ALL FORMS EXCEPT CLL

5 REMS AT AGE 20 (50% TO MARROW)

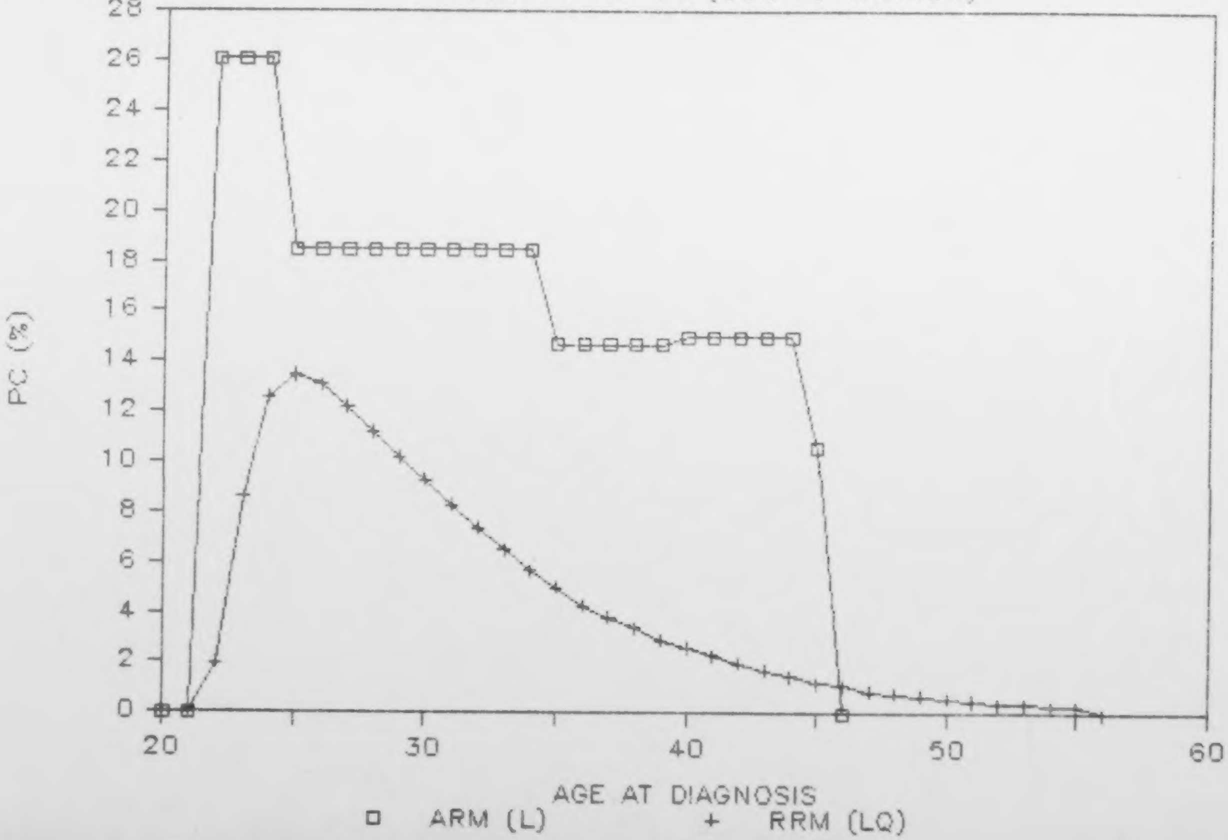


FIG.4

LUNG CANCER

5 REMS AT AGE 20 (50% TO LUNG)

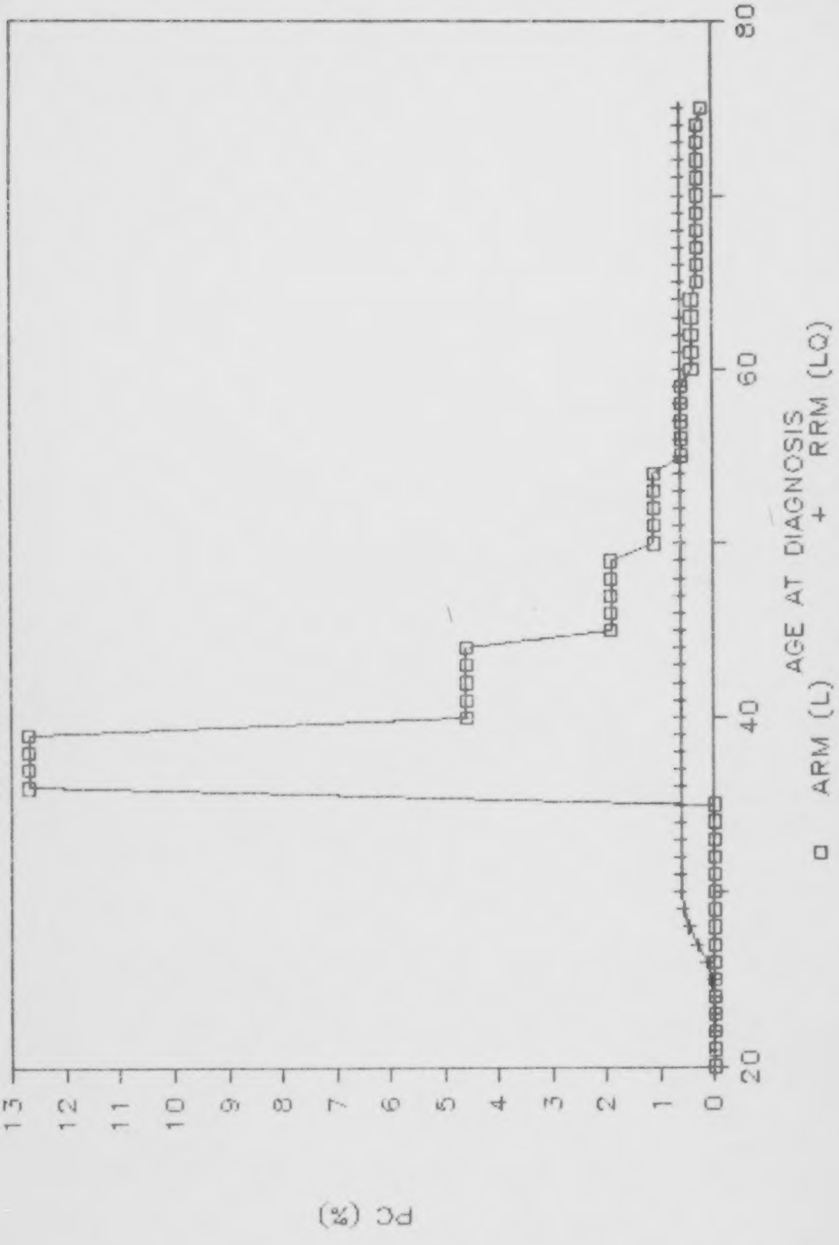


FIG.5

LUNG CANCER

5 REMS AT AGE 20 (50% TO LUNG)

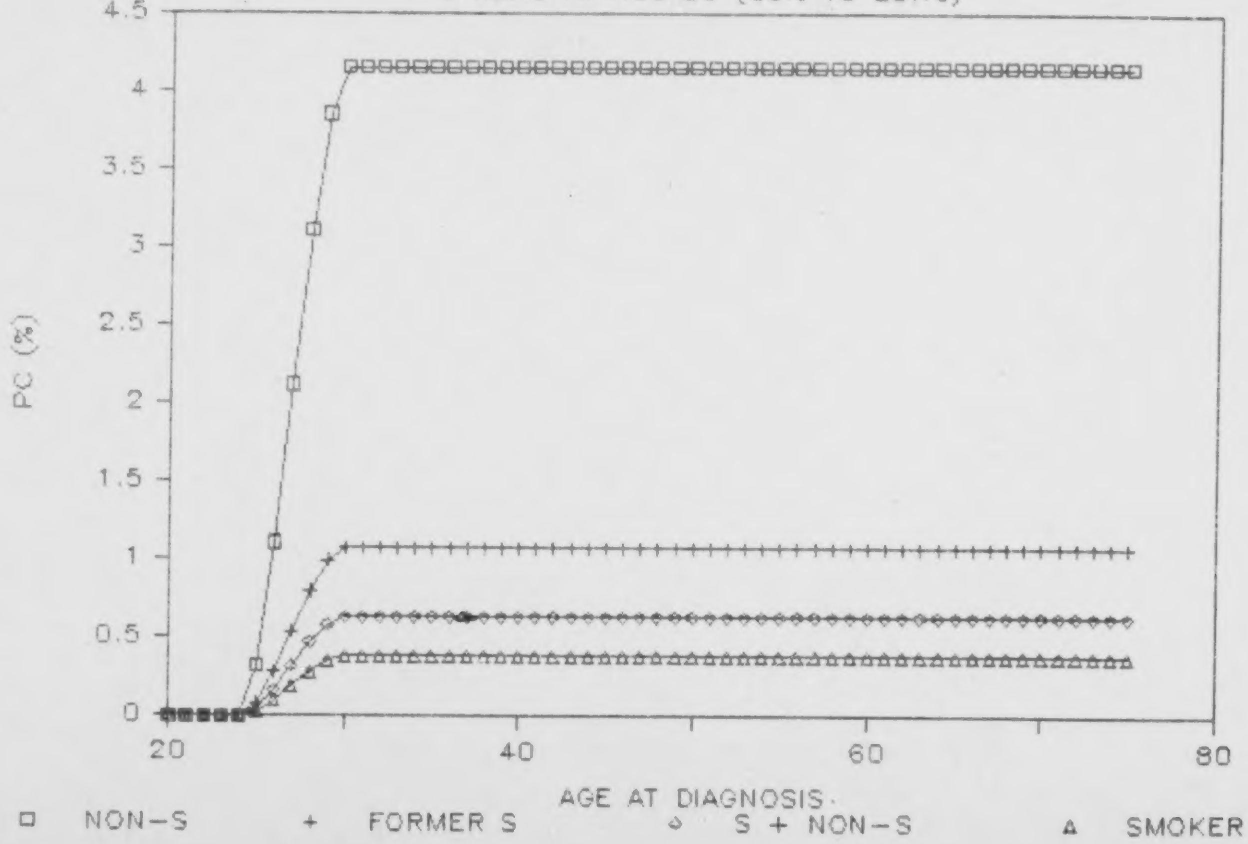


FIG.6 LUNG CANCER — PROB. OF CAUSATION

1 REM/YR (50% TO ORGAN), LOW LET

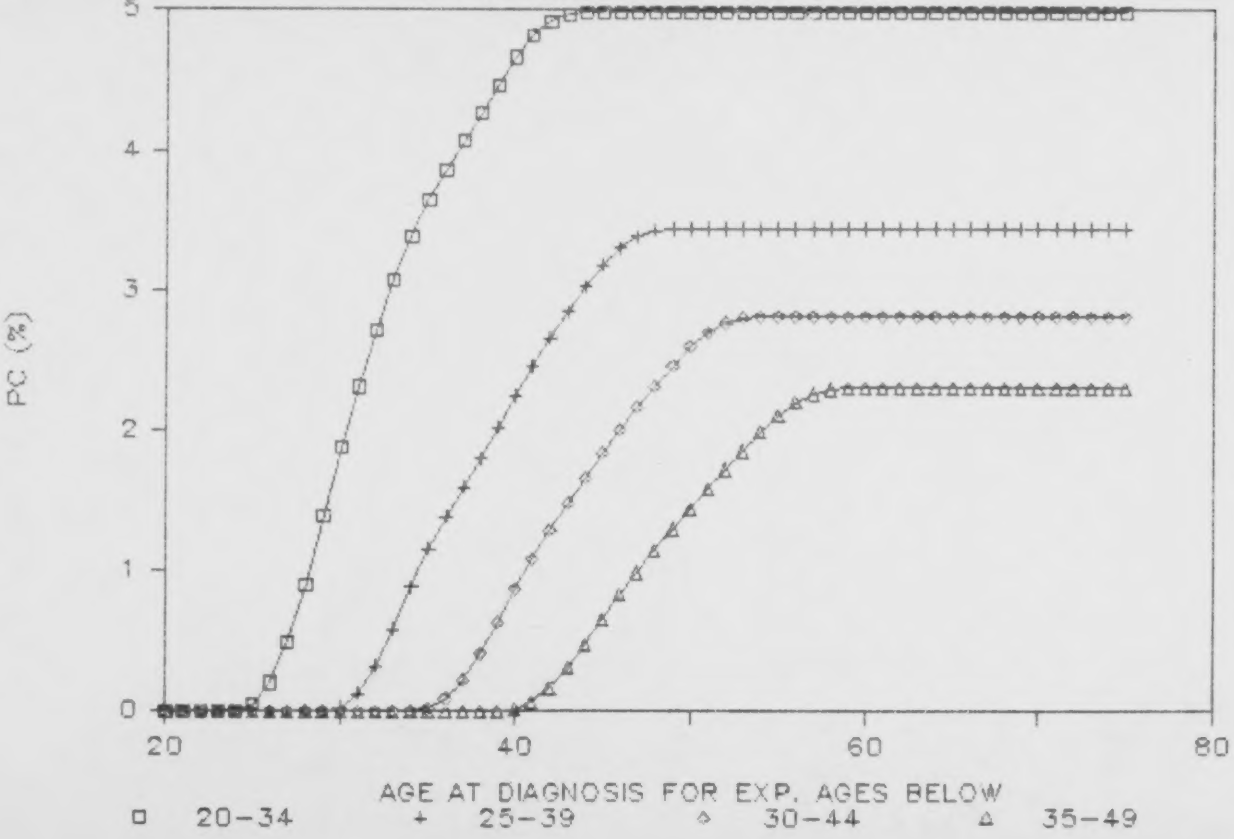


FIG.7 THYROID CANCER — PROB. OF CAUSATION

1 REM/YR (50% TO ORGAN), LOW LET

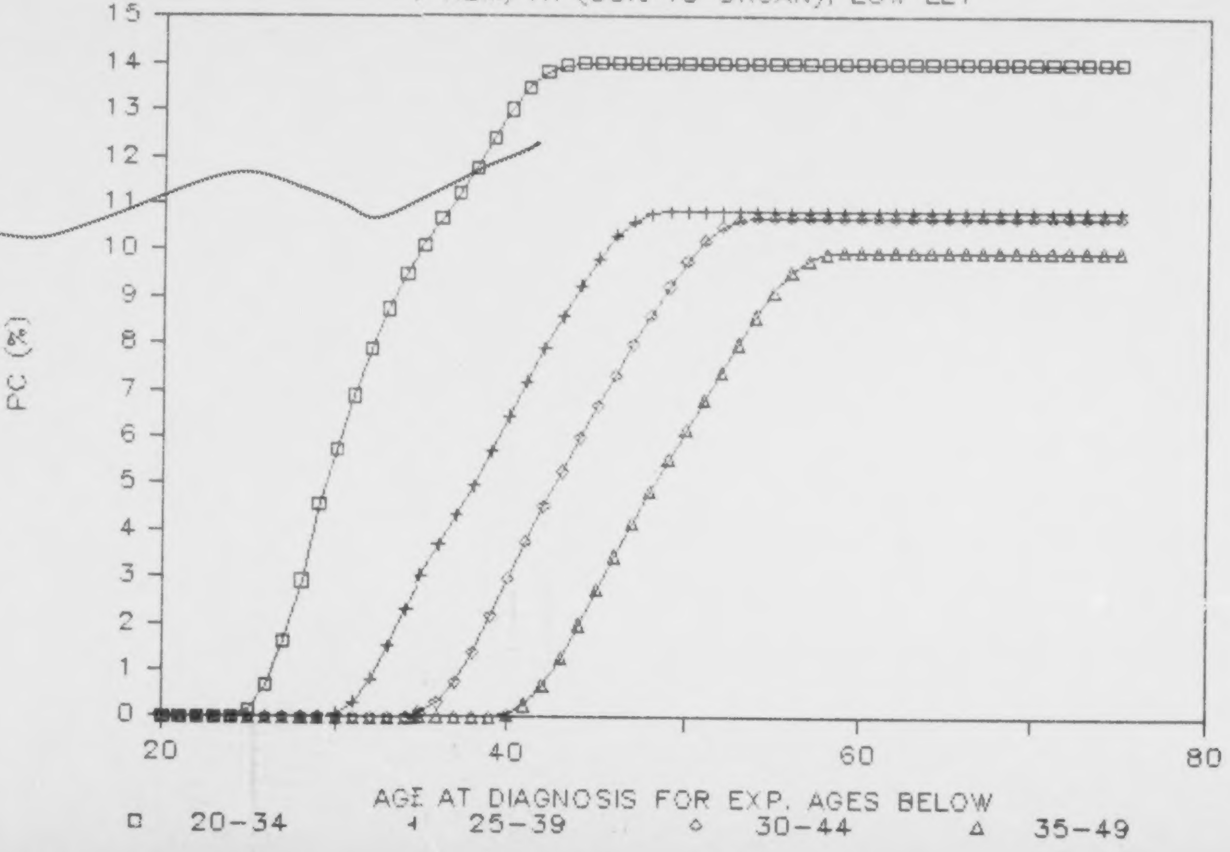
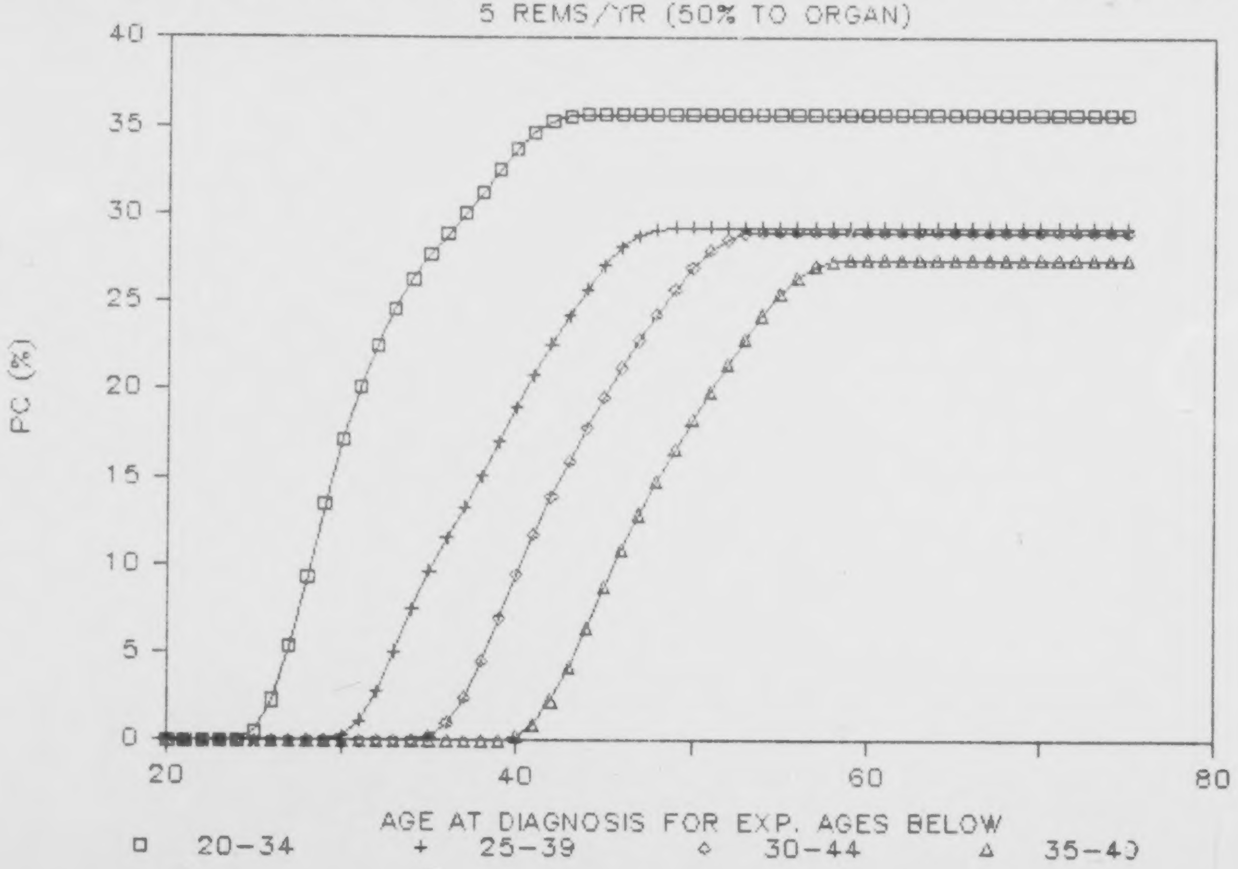


FIG.8 THYROID CANCER — PROB. OF CAUSATION



QUESTIONS FROM SENATOR HATCH FOR ROBERT CATLIN: 10-18-85

1. Presuming that reliance on the tables would lead to a number of awards to nuclear workers, do you think that this use of the tables would undermine radiation safety standards?

Answer: Use of the tables potentially could lead to a tightening of radiation exposure standards but this is by no means certain. There should be no effect on the safety of reactors or other facilities.

Discussion: Except for high exposure situations, e.g., exposures of early U.S. uranium miners or individual cases of acute accidental exposure, cancer incidence in nuclear workers does not exceed that in matched, unexposed populations. Under present Federal standards and industry practices, few if any nuclear workers will exceed or even approach a 50% probability of causation level from occupational exposure. However, were the criterion for compensation set at much lower levels, on the order of 10-20%, and should this action result in a significant increase in the number of individuals compensated (even though 80-90% of the cancer cases would have arisen from natural incidence causes), economic pressures to reduce the levels of exposure received would likely develop. This consequence could also affect public acceptability of the radiation exposure standards, whether or not the projected levels of risk per radiation exposure remain unchanged.

In considering the above conclusions, one must recognize that the driving force engendered by industry/Nuclear Regulatory Commission ALARA (As Low As Reasonably Achievable) programs has kept radiation exposures of the average nuclear worker and members of the public considerably below the levels of present regulatory standards.

2. Considering that you suggest that proportionately not many cancer victims should have substantial probabilities of causation from nuclear power plant exposures, do you think that it makes sense to compensate people whose probabilities are less than 50 percent - especially in light of the fact that a 50 percent probability implies a 100 percent increase in incidence?

Answer: It depends on the provisions selected for compensation of persons whose probabilities are less than 50%. The difficulty with providing compensation below the 50% probability of causation level is that a substantial proportion of people who were not harmed would be compensated. It is not necessarily correct that a 50% probability estimate for a specific individual correlates to a 100% increase in population incidence.

Discussion: The probability of causation statistic relates to a specific cancer site in a single, statistically average individual. A 50% probability of causation is not equivalent to a doubling of overall cancer risk for an individual because it is linked to a specific site in terms of radiosensitivity and natural incidence rate. For example, whole body exposures leading to a 50% probability of causation for leukemia would result in a much lower probability estimate for any other cancer site. Moreover, only a small number of cancer sites have been included in the NIH Report; many cancer sites (see NIH Report, p. 262) have been excluded on the basis of insufficient evidence of radiosensitivity.

Under current tort law, few nuclear industry workers (or former workers) who get cancer qualify for compensation; this is consistent with the fact that the great majority of such cases arise from sources other than occupational radiation exposure. The question above, whether cancer victims should be compensated where their probability of causation is less than 50%, requires strictly political and societal judgments. There are two considerations which pertain to such judgments: the first is the effect of incentives to protect workers. Current standards and regulatory practices (including optimization and ALARA procedures) provide strong safety incentives, as the fact that few workers who get cancer have significant probabilities of causation indicates. For a number of years, the Nuclear Regulatory Commission has followed the policy to value radiation exposure reductions at $ 1,000 per man-rem avoided. This value is on the high end of the range for occupational risk reduction expenditures, and indicates that strong incentives for protection exist in the absence of liability incentives.

The second consideration is whether workers are treated equitably. In a primary sense, equitable treatment refers to the issue of whether nuclear workers are exposed to unusually large occupational risks, for which compensation for low probability of causation values would be justified as an after-the-fact form of hazardous duty pay. The health record of nuclear industry employees clearly does not justify this rationale.

An alternative equity issue is whether the traditional duty to compensate for any caused damages is relieved by the fact that such harm is widely dispersed over a worker population in which it is impossible to identify specific victims or to demonstrate an increase in cancer risk. This is the nub of the political and societal issues to be decided.

It may be useful, in addressing these issues, to ask whether it would be desirable, were it technically feasible, to have such a rule for all occupations. For example, there are reportedly associations between stress and heart disease, or between jobs involving alcohol and the health effects of alcohol use (e.g., cancer, liver disease or traumatic accidents). People required by their jobs to fly frequently can receive radiation and passive cigarette smoke exposures that may jointly produce probabilities of causation which exceed those for many nuclear industry workers. Should all these persons be compensated? Ironically, perhaps the largest long-term health risk, as reflected in longevity data, is unemployment. Occupational health studies frequently observe the so-called healthy worker effect, in which the workers being surveyed exhibit better health, on the average, than a comparable population.

In regard to the above answer, the assumption that a 50% probability implies a 100% increase in incidence would be correct only if the entire population of nuclear workers with cancer were at the 50% probability of causation level - a situation that could not arise because of the application of present radiation exposure standards and management of radiation worker exposures in the nuclear power industry. Such increase in incidence would be wholly unacceptable to workers, employers, health physicists and the public. In today's workforce, the number of workers likely to exceed the 50% probability of causation level is less than one-tenth of one percent.

3. If I understand your testimony correctly, even if the probability threshold were 10 percent, the number of successful claimants would not be crushing to the industry. Is this so? What would the cost be?

Answer: If the probability of causation threshold above which compensation would be awarded were set at 10%, the industry would pay 9 individuals with naturally-caused cancers for every 1 case for which compensation is justified. Adverse impact on the industry would come from two sources: (1) presumption by the public and by workers that all cases in which compensation was paid were caused by occupational radiation exposure and (2) direct costs. If the designated compensation threshold were set at a sufficiently low probability, all employees who get cancer would be led to believe that compensation was deserved, and that their employer was responsible for their cancer. While the number of claimants qualifying at the 10% probability threshold might not be large in any year, a very preliminary estimate of related compensation and damages claims for all U.S. nuclear activities ranges between $ 300 million to $ 600 million per year, based on the proportional compensation schedule originally proposed by Senator Hatch (S 1483). The share for nuclear power might be on the order of one-tenth of this range.

4. What kind of cancers would tend to lead to high enough probabilities of causation to warrant compensation? Are these cancers relatively rare?

Answer: The types of cancer involved, and whether the estimated levels of probability of causation would be sufficiently large to warrant compensation would depend on the probability threshold selected, as well as the levels of radiation exposure received. Assuming a 50% probability of causation compensation threshold, for nuclear power plant workers in the United States, possibly only chronic granulocytic leukemia, and bone and joint cancer would qualify, the latter being relatively uncommon.

Discussion: The numerical levels of the probability of causation depend on numerous parameters, including: (1) the form and primary site of the cancer, (2) the sex of the individual involved, (3) the age at which exposure was received, (4) for leukemia, and bone and joint cancer, the age at diagnosis and (5) the amount and nature of the radiation dose to the organ of interest. Generalizations do not contribute much insight in this regard.

The majority of male radiation workers in nuclear power plants is estimated to receive a lifetime whole body radiation exposure of 10 rems or less. Assuming that a worker begins his exposure experience at age 20, that an organ dose of 10 rems is received by his age at diagnosis, and that the compensation threshold is set at a probability of causation level of 50%, the only cancers that would appear to be eligible for compensation are chronic granulocytic leukemia, and bone and joint cancer, based on the NIH tables. Bone and joint cancer is relatively uncommon (on the order of 2,000 out of a total of about 900,000 new cases per year in the United States [see 1985 Cancer Facts & Figures, American Cancer Society, Inc., 1985]).

5. Do you think that the NIH methodology represents an improvement over the manner in which the courts are currently deciding cases?

Answer: The NIH methodology represents a scientific method for evaluating probable causation that is potentially superior to present practices of confrontation between conflicting sets of "expert" opinion now prevalent in tort law. There are likely benefits from standardization in procedure and in application. Some courts have accepted this new methodology; others have not. The NIH methodology is limited to determinations of likelihood of causation; it does not address other considerations pertinent to compensation award decisions.

6. Your calculations are based upon certain presumptions concerning the doses that are prevalent in the nuclear industry. How credible are these dose estimations, and what are the problems with them?

Answer: My lifetime dose projections are based on summary data published by the Nuclear Regulatory Commission on an annual basis, and on worker exposure experience and working practices reported across the nuclear power industry. These projections appear to overestimate total dose experience to a moderate degree. More accurate projections could be made if lifetime radiation exposure experience was made available for all past and present radiation workers, and if the future course of employment in the nuclear industry could be projected more accurately.

Discussion: Annual whole body dose experience for nuclear power plants is reported on an annual basis by the Nuclear Regulatory Commission in summary form. However, individual lifetime dose experience is not available to the public. In my studies, the distribution of lifetime doses to individual workers, their age and their work experience had to be inferred. The distributions used have been spot-checked against various nuclear worker populations over several years and appear consistent except as follows: (1) in early studies, an exposure period of 20 years was projected for receipt of dose by workers: my present estimates are based on a period of 15 years although the actual value now appears to be as low as 10; (2) the early estimate of worker age at initial exposure was 20 years: 26 years appears to be the present average; and (3) the average annual whole body dose for workers was estimated at about 1 rem: 0.7 rem per year appears to be more appropriate. Thus, my earlier estimates of lifetime dose distributions across the worker population are probably on the high side.

A reduction factor of 0.5 was used to derive organ dose from whole body dose for leukemia, as given in the 1980 BEIR Report. A similar factor was used for other organs: however, these are presumed values which need further verification.

While my calculations are affected by uncertainties in the distribution of exposures, these distributional uncertainties would not be a factor in individual compensation case determinations.

The question of the adequacy of current health physics instruments to predict dose in exposed individuals is too broad for discussion here: a most recent report is NUREG/CR-4239 (July 1985) prepared by Lawrence Livermore National Laboratory for the NRC. Similar studies have been undertaken by the U.S.Department of Energy.

7. Would you advise the nuclear and insurance industries to support the NIH methodology: What would be the benefits of doing so for each industry?

Answer: Whether the nuclear and insurance industries should support the NIH methodology, and whether they will benefit thereby depends greatly on the way in which the methodology is to be implemented. Pending resolution of various deficiencies given in the following discussion, the NIH methodology could be a useful adjunct for causation determinations in possible compensation proceedings.

Discussion: The NIH methodology is a process for estimating likelihood of causation. It is not a surrogate for the overall compensation approach in which the methodology provides only one of the inputs. This method appears superior to other causation estimate procedures for radiation exposure cases, but cannot be applied to many other types of risks, such as most chemicals, due to lack of adequate dose/effect relationship data. The NIH methodology lacks the procedural guidance required for its application, including criteria for determining organ dose, for taking into account factors such as racial or geographical variability, or for taking into account to the necessary degree factors particular to the individual (such as lifestyle, diet, smoking habits or family traits). Also, more extensive review is needed of the epidemiological analyses from which the NIH table parameters were derived, and of the treatment of uncertainties. For these reasons, the NIH methodology as a causation estimation input can be supported now only in a provisional manner. Should these deficiencies be resolved, the nuclear and insurance industries may find the NIH methodology to be a useful adjunct for causation determinations in possible compensation proceedings.

Unlike an overall radiation exposure compensation protocol, the NIH methodology represents only one limited component. Also needed are the bases for qualifying individuals for possible compensation and for determining fault or negligence, the probability thresholds at which compensation may be awarded, and the process for setting the amount of compensation that may be given.

8. How would you see the tables and the NIH report used?

Answer: Assuming that the issues of how to validate and apply this methodology are fully resolved, the NIH report, including the radioepidemiological tables, should prove most useful when applied as formal guidance for the determination of likelihood of causation in radiation exposure cases, either in compensation law, in administrative remedy, or in court proceedings. In so doing, care must be exercised to ensure that legal or legislative constraints relative to adopting this methodology do not diminish its technical adequacy or distort current norms of accepted legal process.

QUESTIONS FROM SENATOR SIMPSON FOR ROBERT CATLIN 10-18-85

1. In the report prepared by the Ad Hoc Working Group, the Rall Committee and the Mostellar Committee identified a number of uncertainties associated with the "probability of causation" methodology, and identified those areas where further scientific work is necessary. After reviewing the report, it appears that, in some respects, these uncertainties are rather large. Do we know enough, at this stage, to use this approach as a basis for compensating individual cancer claimants, or would we be better off if we took the time to address these remaining uncertainties?

Answer: The uncertainties given in the NIH Report are rather large for probability of causation levels in the central range of, say, 10 to 90 percent. These combined uncertainties and the radioepidemiological relationships on which they are based are given only in summary form in the NIH Report. A more rigorous review by the scientific community should be made of the dose/effect relationships used, the degree of fit to epidemiologic data, the derivation of the uncertainty distributions and the manner in which such distributions were combined.

Discussion: Even after such review, the residual uncertainties are certain to remain significant. Despite extensive epidemiological research, it is not known whether radiation exposure up to a total of 10 to 20 rads over many years poses any additional cancer risk. No foreseeable research appears likely to remove this uncertainty. Present dose/risk relationships have been derived on the basis of extrapolations below the range of scientific knowledge on two bases. First, dose/risk relationships currently used in present standards for protection of nuclear workers and the public from exposure to ionizing radiation are derived on a conservative "upper bound" basis: the true value of risk ranges from zero to this "upper bound" level. Second, dose/risk relationships developed in the NIH Report for causation/compensation applications have a "best estimate" base: the true value of risk ranges from zero to the "best estimate" level. Thus, the "best estimate" level constitutes a different type of upper bound of risk which, for low-LET radiation, is lower than the "upper bound" level. Use of the NIH risk factors generally leads to lower probability of causation derivations than do the conservative risk relationships which form the basis for present radiation protection standards and which, by default, have been used in compensation cases prior to the NIH Report.

(Catlin to Sen. Simpson, 10-18-85)

Some factors contributing to uncertainty require further years of observation for improvement; other contributors either lie beyond present observational capability or are of such nature as to escape resolution. For example, a specific individual who has cancer may be related to a statistically average individual in a comparison population by attributes such as race, geographic location or smoking habits: attributes whose uncertainties may be reduced by further investigations. But it may not be possible to ascertain to the desireable degree the effects and uncertainties of personal attributes such as lifestyle, familial traits, or the statistical inaccuracies encountered as the comparison population is narrowed to match the characteristics of the specific individual more closely.

Because the "best estimate" approach used in the NIH methodology also represents an upper bounding of risk, probability of causation determinations may be overestimated, despite the uncertainty ranges given in the NIH Report. Thus, it may be prudent initially to accept the uncertainties in the NIH approach and to address the issues of implementation while such uncertainties are being reexamined. In any event, very few radiation workers or members of the general public with cancer appear likely to achieve a probability of causation exceeding a few percent from industrial applications of nuclear energy.

2. What are the potential impacts of this methodology--and any proposed system of compensation based on the "probability of causation" tables--on the way in which we establish radiation protection standards for the commercial nuclear power industry?

Answer: The impacts of any possible system of compensation based on use of the NIH tables cannot be addressed until such systems are defined. However, the associated risk assessment coefficients and modeling can be used to show the degrees of conservatism in controlling risks under present radiation protection standards and industry practices.

Discussion: The NIH methodology relates to the sole issue of probable causation of cancer by prior radiation exposure - only one of the elements involved in liability/compensation determinations. It does not define which individual or class of individuals should be compensated, nor does it address the decision criteria for making awards or the size of awards: such factors involve strictly political and societal judgments. Moreover, use of the NIH methodology constitutes a probabilistic approach conceptually innovative for much legal practice.

Whether or not the NIH probability of causation methodology is adopted in compensation systems, the risk assessment coefficients and modeling developed by the NIH Ad Hoc Working Group will likely impact the development of radiation protection standards for both workers and the general public. Conservatisms have been routinely applied in the application of dose/risk relationships in developing radiation protection standards and guides. These conservatisms have been amplified by additional conservatisms in converting the guidance to regulations. An initial measure of the overall safety factors inherent in present radiation safety regulations can now be estimated with the NIH risk projection modeling. Some degree of conservatism in radiation protection standards is warranted; such an estimate can show if it is adequate, appropriate, and not excessive.

3. What impact will there be, in your judgment, if we establish a system to compensate individuals in one context where, in a different context, an exposure of that same amount is within Federally-permitted limits?

Answer: This situation already exists. No health protection standards embody zero risk. Compliance with NRC, OSHA or other health standards does not preclude liability, compensation or even punative damages. A modicum of risk is acceptable to society and is generally low in radiation protection for workers compared to other occupational risks, generally.

Discussion: Federal standards for limiting exposure of workers and the public to ionizing radiation are based on the prospective risk of developing additional adverse health effects such as cancer. These risks are extremely low - on the order of one chance in a million to one chance in ten million per year for an average member of the public.

Probability of causation estimates are based on retrospective risk: that is, they relate only to individuals in whom cancer has appeared, and who had received prior radiation exposure additional to background. Because Federally-permitted limits do not assure an absolute level of safety, a few additional cancer cases might be expected to appear under such standards, in addition to those occurring spontaneously or as a result of radiation exposures from medical practices, exposures to chemicals and so forth. These added cancer cases cannot be distinguished from those occurring from natural causes, nor can the excess be identified by statistical methods as a change in current incidence rates. Any new system of compensation that uses a "more likely than not" test of causation would be unlikely to change this situation.

However, if any proposed system for compensation of cases involving radiation exposure would substantially increase the numbers of persons compensated (by using, for example, a probability of causation floor as low as 10 or 20%), public reaction would likely force a reduction in the levels of the radiation protection standards, even if no excess was observed in the incidence rate. A similar situation would likely arise if extremely conservative radiation protection standards were adopted: the public would interpret the action as proof of substantially increased risk, even though cancer incidence remained unchanged. Such probable impacts merit careful consideration when establishing compensation systems for radiation exposure cases and weighing the merits of proposed changes in radiation protection standards.

4. The Veterans Administration is currently considering whether it should employ the "probability of causation" methodology in the regulations that it is now developing under the "Veterans Dioxin and Radiation Exposure Compensation Standards Act." Do you support the use of this methodology by the Veterans Adminstration in that context?

Answer: Yes, as guidance for use in radiation exposure cases but with certain reservations, given below. (The probability of causation guidance in the NIH Report is not relevant to dioxin).

Discussion: Similar methodology has already been used as guidance in Canada (Atomic Energy of Canada, Limited) and in Great Britain (British Nuclear Fuels,Limited) for settlement of radiation compensation claims. However, the NIH methodology does not contain the procedural guidance needed for its application, including methods for determining organ dose, for taking into account factors such as race or geographic variability, or for taking into account individual characteristics such as lifestyle, diet, smoking habits, familial traits or medical radiation exposure history.

Moreover, the NIH methodology addresses only the issue of causation. Other considerations for which additional guidance is needed involve criteria for establishing which individuals qualify for possible compensation, for determining fault or negligence, and for deciding when a person is to be compensated and at what level. Whether the NIH methodology can be successfully and equitably employed by the Veterans Administration will be governed by the procedural criteria and other protocols that are established for radiation exposure cases.

5. If I understand the logic of the "probability of causation" approach to compensating individuals exposed to radiation, wouldn't it be possible, if we endorse this approach, for an individual with, say, a 30% "probability of causation" that his cancer was caused by radiation to recover 30% of a full award, and then later bring a lawsuit alleging that his cancer was the result of, say, benzene exposure--and, if he could then demonstrate a 50% or greater likelihood of that, thereby meeting the normal tort standard, then recover a full award for the benzene exposure? Have we not then compensated this individual for 130% of his claim?

Answer: Such recovery is of course possible, depending on the vagaries of possible compensation schemes and judicial decisions. Under any well-designed probability of causation methodology, the total effect of all carcinogenic risks to an individual cannot produce more than 100% of any one cancer, i.e., the total probability of causation cannot exceed 100%. However, if the overall compensation scheme is not adequately designed, any combination of awards becomes possible. The situation becomes more complex when there are multiple claims, multiple defendants, multiple jurisdictions, or a combination of workmen's compensation and tort claims.

Senator SIMPSON. Dr. Lapp, please.

Dr. LAPP. Thank you, Senator.

I am a physicist, currently consulting with the nuclear power industry as a radiation protection specialist. I wrote my first book, "Radiological Safety," in 1948, began my radiation experience in 1940.

I appear here today to give you a perspective on radiation risk with specific applications to the nuclear power industry. I take a hardhat approach here, because I am using actual data, printout data, from specific plants on the lifetime doses of workers acquired during a certain number of years. And I am going to be able to compress my written testimony from four pages to one, and in fact, less, because yesterday it was stated before this committee that if you took 1,000 persons and exposed them to 5 rad of radiation per year for 40 years, you would end up with an excess of radiation-induced leukemia of 4.5 cases. I would like to put that in perspective, because 4.5 radiation-induced leukemias out of 1,000 is certainly a significant number, especially considering the traumatic effects of leukemia on a person.

It turns out that this means a whole body dose in the persons in the hypothetical example of 400 radiation units or rem. Believe me, I worked at over 20 nuclear units, and we have no workers in that range. Very rarely do I ever see a worker with more than 40 rem, and the average for a specific plant, in which I have data on 1,500 workers, is closer—and it is a good plant—to 4 rem for the lifetime dose.

Now, through using very simple arithmetic for this example, of 1,400 workers, with an average of 4 rem for lifetime dose, I am able to convert the data that you were given yesterday of this extra 4.5 cancer deaths, I am able to convert that into the risk for a single plant, a real plant, where I have actual data from which I can extrapolate lifetime exposures.

The worker's average age is 26 on first exposure to radiation; the average worker today is 35 years of age—a fairly young population group. The worker has about one-tenth-percent chance of contracting fatal cancer in the next 10 years; it doubles in the next 20, but will become 24 percent, ultimately.

So that out of a population of 1,000 people, we will have perhaps 240 people ultimately get cancer. How much of that could be radiation induced?

I have made the following calculations. In this particular case (table IV), I calculate that the plant work force of 1,400 men through the year 2060—because I extrapolate through the entire length of the plant, plus the life of the worker—to the year 2060, and that would leave 332 cancer deaths, assuming no radiation exposure.

Using just leukemia, I am able to project two-tenths of a cancer death due to radiation. And since there will be 1,400 deaths in a work force of 1,400, this zero two-tenths leukemia deaths would be a ratio of one chance roughly in 10,000. The total cancer mortality, based on a 4:1 cancer to leukemia ratio, would still be less than one death in a workforce of 1,400.

I submit this is a very small risk. The average nuclear worker has a much greater risk of being electrocuted, and he has a hundredfold greater risk of dying from lung cancer. Smoking for a nuclear worker is 100 times the normal radiation risk calculated on a lifetime basis.

These, I think, Senator represent real data, real estimates, and I will tell you they do not depend just upon the Hiroshima and Nagasaki data, but in fact, my key for calculation is based upon 14,400 British men and women, young men and women, who were x rayed, five applications of 100 rad each to the spinal column to relieve ankylosing spondylitis which is, as you know, an arthritis of the spine.

And we have followup data on the spondylitis, which is not going to be affected by the Hiroshima or Nagasaki data. So it is quite independent. Thus, I believe we can scope the damage, and I believe what it amounts to is that we have established extremely conservative radiation standards, and furthermore, the nuclear industry, through the regulation by the Nuclear Regulatory Commission, has policed its radiation protection activities in such a way as to get just a small amount per worker of the annually permitted nuclear radiation.

Thank you, Senator.

Senator SIMPSON. Thank you very much.

[The prepared statement of Dr. Lapp and responses to questions submitted by Senators Hatch and Simpson follow:]

U.S. SENATE COMMITTEE
LABOR & HUMAN RESOURCES
HEARING ON HHS RADIATION TABLES

RALPH E. LAPP
12 JUNE 1985

ASSESSMENT OF NUCLEAR RISK

The Tables contain many examples of risk assessment for single or a few multiple doses of ionizing radiation for medical diagnosis or treatment. They involve irradiation of both sexes at many different ages. Occupational exposure in the nuclear power industry is confined largely to adult males and involves irradiation distributed over a number of years. To assess radiation risk for nuclear workers over their lifetime it is necessary to define both the radiation doses and the ages when exposure occurred. The U.S. Nuclear Regulatory Commission has very little lifetime dose data and I will draw upon my experience at a number of power reactor sites to assess typical worker risk. My evaluation will be confined to male workers - specifically those employed directly by the utility. These are known as utility/plant workers.

Data collected for 2,500 workers having a lifetime dose over 1 rem indicates an average age at first exposure to be 26 years. The present age of these workers is 35. Although annual doses received vary from unit to unit, I find that the average exposure is about 0.7 rem per year. Data collected at units operating for a decade indicate a lifetime dose for workers receiving more than 1 rem is about 6 rem per worker. I will assume for purposes of computing probabilities of causation that the representative dose schedule is 0.7 rem/year beginning at age 26 and terminating at age 35, corresponding to a lifetime dose of 7 rem. Bear in mind that I have restricted discussion to workers accumulating more than 1 rem in their career. If we take into account the workers who do not receive 1 rem then the average lifetime dose for all workers is much smaller than 7 rem.

Using these numbers and assuming that a worker is diagnosed as having a radiosensitive cancer by age 65, I use the NIH Tables to calculate the probability that the malignancy was caused by 7 rem of ionizing radiation. Table I presents the results for 11 cancers; salivary gland cancer is omitted because of its rarity.

TABLE I

Cancer	Probability of Radiation Causation
Leukemia	0.5%
Bone	1.4
Esophagus	0.3
Stomach	0.9
Colon	0.3
Liver	3.0
Pancreas	0.6
Lung	0.1 to 1.3
Kidney/Bladder	0.2
Thyroid	3.9

In the case of lung cancer, a pack-a-day smoker has a 0.1% PC as opposed to 1.3% PC for a non-smoker.

Another way of looking at the data is to calculate the lifetime dose required to yield a 10% probability of radiation causation for specific cancers. Table II presents data ranking the relative mortality of the radiosensitive cancers which represent 70% of all malignancies. Table III illustrates the PC's associated with each of these cancers.

TABLE II

Lung/buccal	54%	Esophagus	3.6%
Colon	13	Kidney	3.0
Pancreas	7	Liver	2.8
Leukemia	5.5	Bone	0.6
Stomach	5.2	Thyroid	0.2
Bladder	4.5		

TABLE III

Lung/buccal	60-690	Esophagus	290 rem
Colon	290	Kidney	325
Pancreas	130	Liver	26
Leukemia	150	Bone	55
Stomach	85	Thyroid	20
Bladder	325		

Table III averages out to about 200 rem for a 10%PC if you take into account the relative frequency of cancer deaths as shown in Table II. Taking 7 rem as the average lifetime dose to apply to the NIH Tables, we see that the comparison with doses listed in Table III shows the probability of radiation induction of cancer is very small.

In order to illustrate worker risk I have selected a reactor unit for which there is good dose data. This particular plant ranks in the upper quartile of radiation protection performance, measured in terms of person-rem. Analysis of 9 years of operations shows that for workers with more than 1 rem-lifetime the average exposure is about 4 rem. Allowing for attrition and replacement of the workforce through the life of the unit, I estimate that a total of 1,400 men will accumulate more than 1 rem. Table IV illustrates how their doses would be distributed.

TABLE IV

Dose Interval	Number of Workers
1 - 5 rem	1100
5 -10	200
10 -15	75
15 -20	20
20 -25	5
Total	1400

Only 7% of the workforce would exceed 10 rem lifetime dose and very few would receive more than 20 rem. In general, I would expect that high exposure jobs would taper off as the plant matures. I have urged my clients to adopt a "dose-levelizing" principle, i.e. to set a 10 rem per 5 year exposure period. This has the effect of curtailing above 10 rem lifetime doses.

As noted, the nuclear workforce is young, averaging 35 years of age and at this point the probability that a 35-yr old white male will eventually die of cancer is 23.7%. However, this probability is only 0.2% for the next 10 years and 1.6% for the next 20 years. [H.Seidman et al, CA-A Journal for Clinicians, 35, 36 (1985).]* Thus, 332 of our 1,400 workers will eventually die of cancer. For the period 1985-2060 I use a round number of 300 cancer deaths. Using the criteria of the NIH Tables I estimate that the radiosensitive cancers constitute 70% of all malignancies. This means 210 cancers included in the NIH Tables. Using the data in Table II, I estimate the following number of specific cancers:

TABLE V

Lung/buccal	113 CD	Esophagus	8
Colon	27	Kidney	6
Pancreas	15	Liver	6
Leukemia**	10	Bone	1
Stomach	11	Thyroid	0.4
Bladder	9		

**Adjusted for deaths before age 20.

In order to assess the likelihood that any of these cancer deaths might be attributed to occupational radiation we need to know worker exposure to plant radiation and to off-site sources. In making this assessment I exclude the latter since medical dosimetry is hard to obtain. Therefore, I use Table IV to make this assessment:

LUNG About 85% of all lung cancer is attributed to smoking. However, for this particular plant the smokers constitute about 25% of the workforce. This leaves 85 cancer deaths among non-smokers. A non-smoker with a lifetime dose of 20 rem would have only a few percent chance of incurring a radiation-caused cancer. Only 1 in 280 of the workforce would be expected to exceed 20 rem so there is less than 1% PC for any of the 85 lung cancers being caused by plant radiation.

COLON The high (290 rem) dose required for 10%PC rules out any of the 27 colon cancers as be causally related to plant radiation.

PANCREAS The relatively few pancreatic cancer deaths and the 130 rem for 10%PC combine to show that these deaths would not be radiation-related.

---

*These data apply to any white male.

LEUKEMIA Certain leukemias that involve early age irradiation and expression may have higher probabilities than those calculated in Table I. However, for the workforce at risk to more than 1 rem there will be less than one such case. The probability that such a case might also be a high dose is small.

STOMACH, KIDNEY, ESOPHAGUS & BLADDER The 10%PC for the average of these four cancers is over 250 rem. While they represent 16% of the radiosensitive cancers, these constitute only 2.4% of the subject workforce. Since only 1 in 280 workers would exceed 20 rem, it's clear that the PC for these cancers is about 0.1%.

IIVER This malignancy does involve low rem for a 10%PC. While Table V shows 6 liver cancers the probability that 1 of these would reach a dose level of 26 rem is very small.

BONE & THYROID The 1 and 0.4 cancers indicated in Table V would be too rare to be significant given the dose distribution in Table IV.

The above estimates apply to 1,400 workers with an average lifetime dose of 4 rem. In general, they involve probabilities of causation of less than 1% and often less than 0.1%. I would add here that to be precise one should say 0 to 1% or 0 to 0.1%. I would also note that they may be uncertain by a factor of 2 or 3. This fact does not substantially affect the results since the probabilities are so low.

By the same token, applying the NIH Tables to plant workforces with higher average lifetime doses does not change the risk picture very much. My experience is that a high exposure plant has a projected lifetime dose average of 7 rem.

On any scale of occupational risk, I conclude that nuclear power worker's radiation risk is very small and much less than other common occupational risks. For example, a nuclear worker is more likely to be electrocuted in the course of his career than to succumb to radiation-induced cancer. This may come as a great surprise to members of the public which, in my view, has been grossly misinformed as to the nature of radiation risk.

There are basically three reasons why the nuclear radiation risk is so miniscule.

First, our knowledge of the biological effects of ionizing radiation traces back some 90 years to the days of Roentgen and Curie--to x-rays and radium. Since the early days when overexposure demonstrated acute effects, research has concentrated on the chronic and delayed effects of radiation so that we know much more about this risk than we do about most other risks. Second, safety standards have been set on a very conservative basis. Third, the nuclear industry has exercised strict control of radiation exposure. Utilities spend more than $2 million each year for operational control of this risk at each nuclear unit.

RESPONSES TO SENATORS HATCH & SIMPSON

Simpson-1

Q. In the report prepared by the Ad Hoc Working Group, the Rall Committee and the Mosteller Committee identified a number of uncertainties associated with the "probability of causation" methodology, and identified those areas where further scientific work is necessary. After reviewing the report, it appears that, in some respects, these uncertainties are rather large. Do we know enough, at this stage, to use this approach as a basis for compensating individual cancer claimants, or would we be better off if we took the time to address the remaining uncertainties?

A. [In responding to all questions, I restrict myself to experience in the nuclear power industry. This means dealing with workers in a dose domain similar to that given in Table IV of my statement made before the Committee on June 12, 1985.]

Table I defines probabilities of causation (PC's) for workers with a lifetime radiation dose of 7 rem. It will be noted that for non-smokers, the most common solid tumors are all characterized by a PC of less than 1%. Even if there is a 200% error or uncertainty in the PC estimation, this still yields a very low PC, such that no award should be contemplated.

To delay acting on the NIH Tables until the error band is smaller would allow a mounting precedent in Compensation Boards and in Courts that could make awards on a non-scientific basis.

Simpson-2

Q. What are the potential impacts of this methodology--and any proposed system of compensation based upon the "probability of causation" tables--on the way in which we establish radiation protection standards for the commercial nuclear power industry?

A. The 5(N-18) rule would allow a worker to accumulate 235 rem wholebody lifetime dose if exposed to 5 rem/year through age 65. I have postulated an "average" dose schedule, i.e. that for the average nuclear worker as being an annual exposure of 0.7 rem protracted over a decade beginning with exposure at age 25. This 7 rem lifetime dose is 34 times smaller than the 235 rem lifetime dose allowable under the 5(N-18) rule. I conclude that the 5(n-18) rule is very conservative when viewed in the light of the nuclear power experience. [Fig. 1 shows that for the most common solid tumors the PC corresponding to full exposure to 5 rem/year is less than 5 percent through age 50.]

Simpson-3

Q. What impact will there be, in your judgment, if we establish a system to compensate individuals in one context where, in a different context, an exposure of that same amount is within Federally-permitted limits?

A. Such a system, in effect, says that "standards are no longer standards." Such compensation would inevitably lead many nuclear workers afflicted with cancer to seek compensation.

Simpson-4

Q. The Veterans Administration is currently considering whether it should employ the "probability of causation" methodology in the regulations that it is developing under the "Veterans Dioxin and Radiation Exposure Compensation Standards Act." Do you support the use of this methodology by the Veterans Administration in that context?

A. Yes. I believe that the PC Tables should be applied in VA cases where veterans claim compensation for injury attributed to ionizing radiation.

Simpson-5

Q. If I understand the logic of the "probability of causation" approach to compensating individuals exposed to radiation, wouldn't it be possible, if we endorse this approach, for an individual with, say, a 30% "probability of causation" that his cancer was caused by radiation to recover 30% of a full award, and then later bring a lawsuit alleging that his cancer was the result of, say, benzene exposure--and, if he could then demonstrate a 50% or greater likelihood of that, thereby meeting the normal tort standard, then recover a full award for the benzene exposure? Have we not then compensated this individual for 130% of his claim?

A. I would think that any compensatory action involving radiation causation would consider the contribution of other carcinogens. The risk term for such contributors would be included in the denominator of the PC equation. But because there is no set of tables comparable to the NIH report for radiation that could apply to benzene, it is not reasonable to expect a quantifiable risk for benzene exposure.

Hatch-1

Q. Presuming that reliance on the tables would lead to a number of awards to nuclear workers, do you think that this use of the tables would undermine radiation safety standards?

A. If reason prevails, use of the NIH Tables as applied to potential claimants in the nuclear industry would indicate little basis for compensation. Only in a very few special situations would I expect there to be compensation awarded to nuclear workers. These cases would be high dose, early diagnosis, highly radiosensitive cancer cases. All three qualifications are rare and lead to even rarer compensable cases.

Hatch-2

A. Considering that you suggest that proportionately not many cancer victims should have substantial probabilities of causation from nuclear power plant exposures, do you think it makes sense to compensate people whose probabilities are less than 50 percent, especially in the light of the fact that a 50% probability implies a 100% increase in incidence?

Hatch-2 A. An estimation of 50% involves a very high lifetime dose for a nuclear worker. For example, if one postulates that the worker receives equal doses of radiation over ages 20 through 40, a 50% PC [R=1] implies a lifetime dose as follows:

Bladder	2758 rem
Colon	2247
Esophagus	2083
Kidney	2758
Liver	177
Lung*	3162
Pancreas	943
Stomach	652

*Average in general population

Since nuclear workers do not experience lifetime doses approaching such as tabulated above, I consider that a 50% PC is unreasonable.

Hatch-3 Q. If I understand your testimony correctly, even if the probability threshold were 10%, the number of successful claimants would not be crushing to the industry? Is this so? What would the cost be?

A. Dr. Robert Catlin is providing a specific response to this question. I would add that any quantified risk estimate has to reckon with the probability that the 10% PC would be contended to have a wide error band that would influence a cost estimate. In general, I believe that the highly radiosensitive cancers, such as leukemia, would be the most contentious. I address these in response to the next question.

Hatch-4 Q. What kind of cancers would tend to lead to high enough probabilities of causation to warrant compensation? Are these cancers relatively rare?

A. The most contentious cases would, in my opinion, be the most radiosensitive cancers as indicated in Table III of my statement. Fig. 2 illustrates the relative incidence of the radiosensitive cancers as detailed in the NIH SEER study of 139,657 malignancies diagnosed in U.S. white males from 1973-1977. Thyroid incidence [blue curve] dominates the risk scene during the early career years along with leukemia.

Fig. 2 displays the same data on a linear scale over ages 20 to 60. Bone and liver cancer are quite rare in the pre-retirement years and will be neglected here. The incidence of thyroid cancer demands attention, especially for nuclear workers exposed to radioiodine uptake. Here, I note that this particular cancer is rarely fatal. This is

Hatch-4 A.

illustrated in Fig. 4 where mortality, as opposed to incidence, data are plotted. In the survey population only 1 death due to thyroid cancer was found for the 20 to 40 year age group. This does not mean that thyroid cancer would not be a candidate for litigation. In Allen, one claimant was awarded $100,000 in damages attributed to a thyroid adenocarcinoma diagnosed at age 21.

In the 20 to 40 year age bracket white males exhibit a thyroid cancer diagnosis for 6% of all malignancies observed. If we focus upon cases diagnosed among the 20-40 year old males in a lifetime of plant workers stretching through the lifetime of the plant, namely 1,500 total workforce used in my testimony we would project 9 cancer cases. There would be a 50% probability that one of these workers might have a thyroid cancer. It is highly unlikely that such a cancer case would have a radiation dose sufficient to induce the malignancy.

This means that leukemia emerges as the malignancy of concern in the early career ages. One way of scoping this cancer risk is to note that 4.5% of all cancer deaths are due to leukemia. This that in the 237 cancer deaths projected in a population of 1,000 workers, 10.7 leukemia deaths would be expected. Multiplying this number by 8.7% [the number of workers aged 20-40 divided by workers over 20 who die of leukemia] yields 1 early leukemia death.[The age dependency of leukemia mortality is illustrated in Fig.5]. The probability of causation in leukemia cases depends not only on dose but on when exposure ocurred and when the disease is diagnosed. For lifetime doses under 10 rem the PC would be unlikely to exceed 30% except for the very few cases of diagnoses under 30 years of age.

Hatch-5 Q. Do you think that the NIH methodology represents an improvement over the manner in which the courts are currently deciding cases?

A. Yes. I believe that the NIH Report provides the courts with an objective assessment of radiation causation as viewed by a group of experts with long experience in the field. The Tables give courts a "mainstream" view of radiation risk against which the opinion of a single expert witness may be judged.

Hatch-6 Q. Your calculations are based on certain presumptions concerning the doses that are prevalent in the nuclear industry. How credible are these dose estimations, and what are the problems with them?

A. Data given in Table IV of my statement represents actual dose experience observed at nuclear power units in operation for more than 9 years. I believe the data to be reliable.

Hatch-6 A. (Cont.)

I believe that the data base truly reflects the lifetime radiation exposure of the plant workers. There is some uncertainty in using a 9 year data base to project to 40 year life of plant workforce exposures. I assumed a factor of 7% attrition of the workforce and no increase in plant complement beyond its 1984 level [data refer to all workers with more than 1 rem lifetime dose.] I did not take decommissioring into account.

Hatch-7 Q. Would you advise the nuclear and insurance industries to support the NIH methodology? What would be the benefits of doing so for each industry?

A. Yes, I would advise both industries to adopt use of the NIH Tables. I think that it would have a beneficial effect in reducing litigation costs since the Tables can be used to screen out meritless cases.

I think that the Tables deserve to be "translated" into a form that can be readily understood by the average nuclear worker. Indeed, I would suggest that the Congress request that the NIH prepare and publish such a report. One of every four nuclear workers will die from some type of cancer and it's only natural that many may believe that nuclear radiation was causative. As my testimony indicated, I think that the radiation risk is extremely small. However, the risk is much publicized by the media and, as a result, many workers may be confused. I believe that there are graphical ways to illustrate the risk* so that a worker can perceive relative risk rather easily.

Hatch-8 Q. How would you see the tables and the NIH report used?

A. As explained in my response to the previous question, I think that the report forms a credible basis for putting radiation risk in perspective. The report can be used as an educational vehicle and it can be used by expert witnesses in testifying both for plaintiffs and defendants.

---

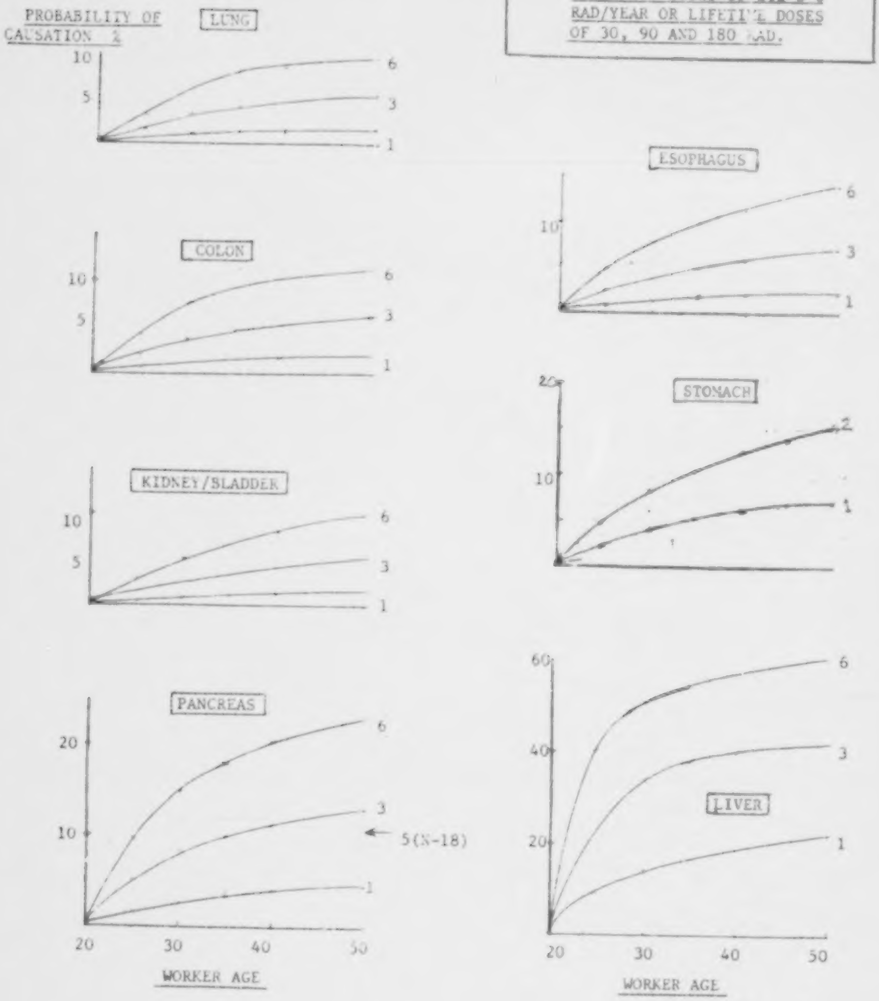
*Enclosed is Fig. 2 showing the relative radiosensitivity of the most common cancers as reflected in the K-factor, which in turn translates into PC as shown in Fig. 3 for stomach cancer.

NOTE: All incidence and mortality estimates for radiation-attributed cancers represent extrapolation to low doses in a domain where the real numbers may in fact be zero or near-zero.

Fig. 1

DATA SOURCE: NIH RADIOEPIDEMIOLOGICAL
TABLES (PUBLICATION 85-2748)
MARCH 1985

PROBABILITY OF CAUSATION
FOR COMMON RADIOSENSITIVE CANCERS
FOR WORKER AGES 20 TO 50
FOR ORGAN DOSES OF 1,3 & 6
RAD/YEAR OR LIFETIME DOSES
OF 30, 90 AND 180 RAD.



zREL850312

Fig. 2

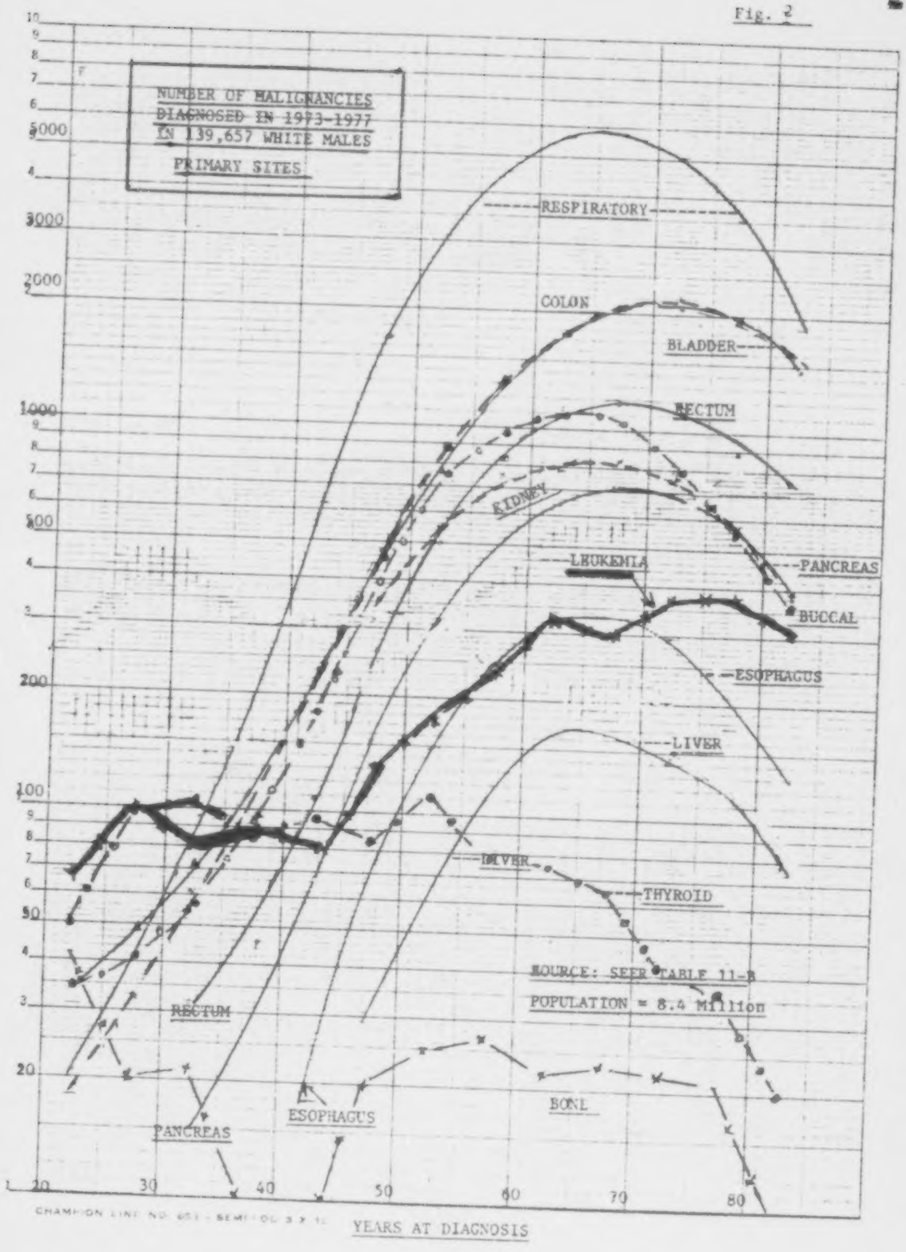
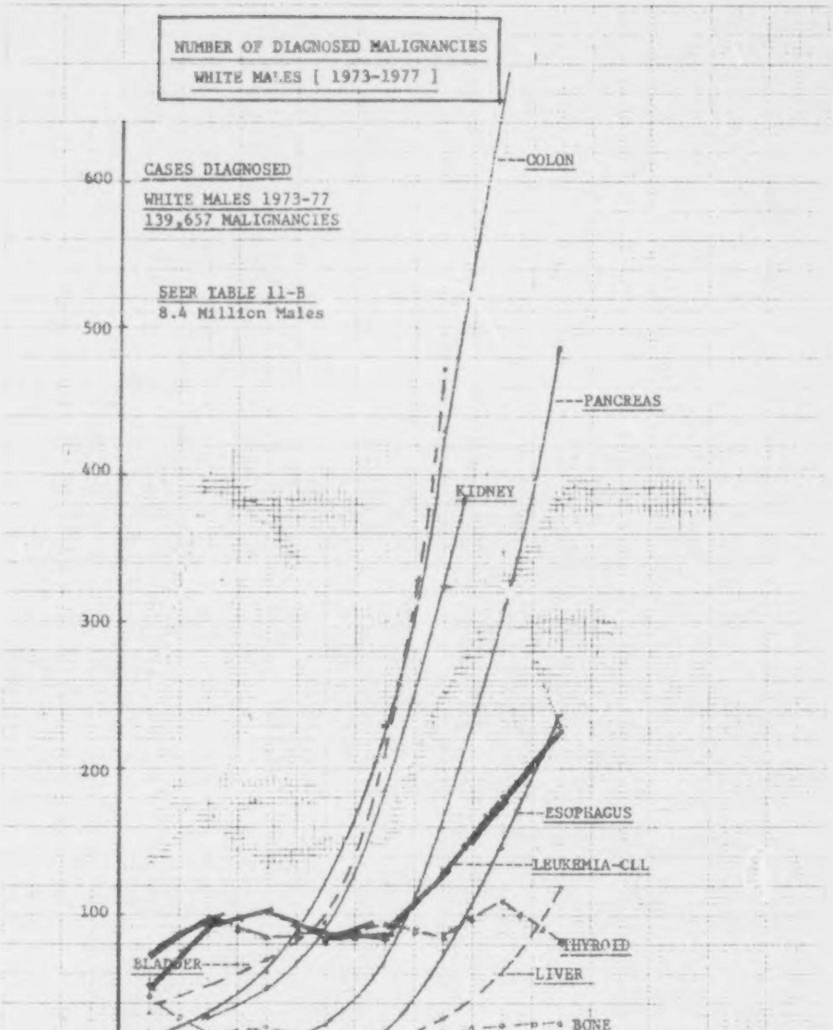
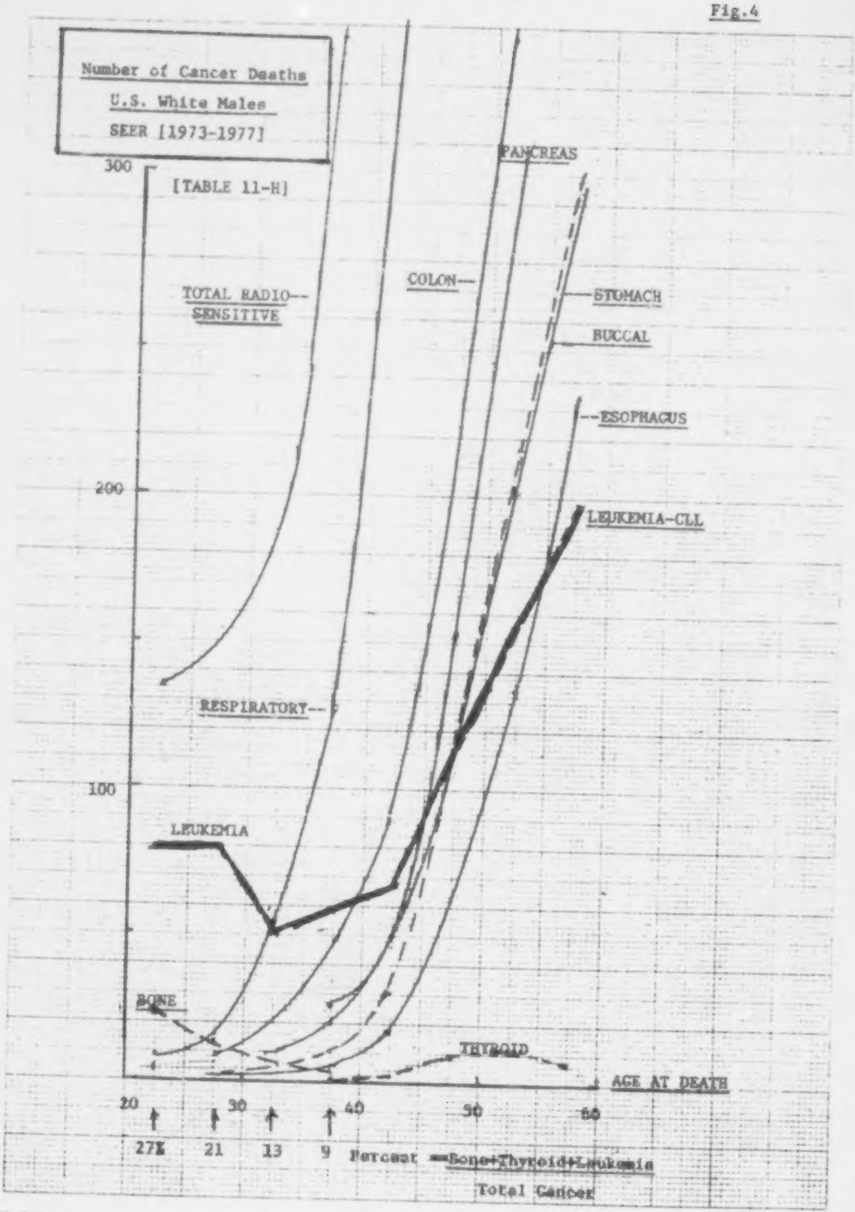

NUMBER OF MALIGNANCIES
~~DIAGNOSED IN 1973-1977~~
IN 139,657 WHITE MALES
PRIMARY SITES
RESPIRATORY
COLON
BLADDER
RECTUM
KIDNEY
PANCREAS
LEUKEMIA
BUCCAL
ESOPHAGUS
LIVER
THYROID
RECTUM
PANCREAS
ESOPHAGUS
BONE
SOURCE: SEER TABLE 11-B
POPULATION = 8.4 Million
10
9
8
7
6
5000
4
3000
2000
1000
9
8
7
6
500
4
3
200
100
9
8
7
6
50
4
3
20
1
20
30
40
50
60
70
80
CHAMPION LINE NO. 653 - SEMI-LOG 3 X 11
YEARS AT DIAGNOSIS

Fig. 3



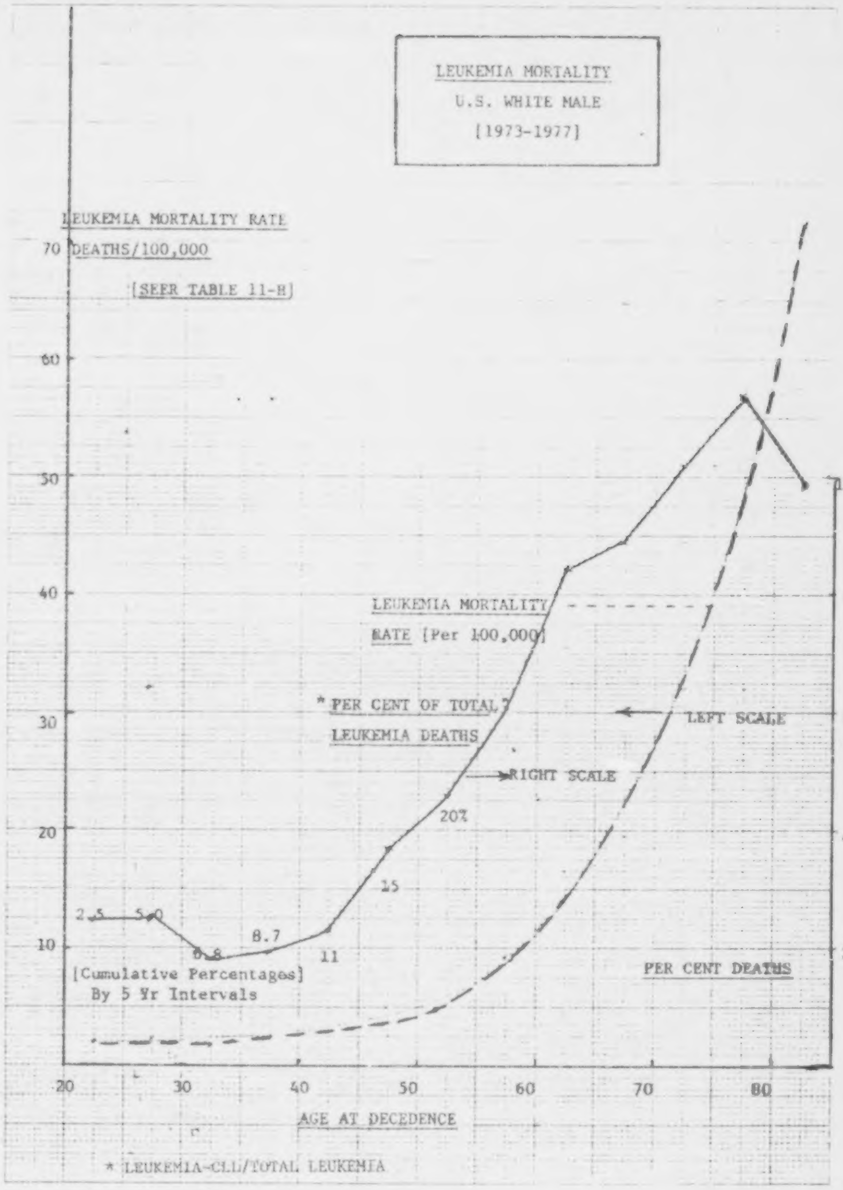
20 Squares to the Inch

Fig.4



25 Squares to the Inch

Fig. 5


LEUKEMIA MORTALITY
U.S. WHITE MALE
[1973-1977]
LEUKEMIA MORTALITY RATE
DEATHS/100,000
[SEER TABLE 11-8]
70
60
50
40
30
20
10
10 %
8
6
4
2
LEUKEMIA MORTALITY
RATE [Per 100,000]
LEFT SCALE
* PER CENT OF TOTAL
LEUKEMIA DEATHS
RIGHT SCALE
2.5
5.0
6.8
8.7
11
15
20%
[Cumulative Percentages]
By 5 Yr Intervals
PER CENT DEATHS
20
30
40
50
60
70
80
AGE AT DECEDENCE
* LEUKEMIA-CLL/TOTAL LEUKEMIA

Senator **Simpson**. Thank you very much.

You and the previous two witnesses, Mr. Cooper and Ms. Tucker, quickly portray how we got to this point. You have to use numbers, and yet you are talking about human beings. And so, in this terribly frustrating arena, where you go to court, and you do not receive anything because you haven't got the right numbers on your side, you haven't got tort law on your side, you come to Congress. And we do not solve anything very well, and the groups out there in the land do not solve it themselves, because we happen to be galloping around, handling about 600 issues at one time, and we cannot direct our full energies and focus to a singular issue which is of critical importance, such as this.

Now, I have been in enough of these, dealing with my areas of immigration and refugees and nuclear regulation and veterans' affairs and agent orange, to watch how this place is sometimes overwhelmed with issues of guilt, fear, emotion, and racism. And then you have to come along, thoughtful Republicans and Democrats, come along behind that and prove up. It is a difficult arena, and it is not a fun arena, because appetite and ambition compete openly with knowledge and wisdom. It is a hell of a dingy place to work.

So, in that process, we do have to deal with numbers. I wish we did not; we could just say that there is a wretched human condition, and it must be compensated, and even if we cannot quite prove it, it should tug at our heartstrings to a point that we should. Would that we could do that, and we do respond pretty well that way in most things.

Enough of that. But it is a tough issue, and I will be waiting to compare these figures, these interesting figures that you have given me from live human beings in a very interesting array of presentation, with the figures Mr. Brown will present and Ms. Tucker, which I assume will be quite clear and verifiable—at least, they believe that they will be so; that is what they have testified. You believe that yours are so, and we will look at that. That is our task.

Let me ask you, because I do get involved in the area of commercial nuclear activities, and I am particularly interested in the potential impact of these tables that we are speaking of here in this proposal, on the radiation protection standards of the industry, particularly in the mining, milling, working arena, which has been approved not by the miners and the millers and the utilities, but by the United States of America, and the NRC, and the EPA, and so on.

What are the potential impacts of this methodology on the way in which we now establish and have on the books radiation protection standards?

Mr. **Catlin**. As you know from yesterday's testimony, the National Academy of Sciences has a group which is set up to look at this problem of high-LET exposure, and the risk assessment information to be gleaned from it. My view is that at the present time, we have uranium mining standards, that is, standards for protection against radon and radon daughters, which have largely been derived from epidemiological evidence that comes from the experience in the Colorado plateau. This is information which perhaps has to be harmonized with what is going to come out of Hiroshima and Nagasaki. But I simply do not see any substantial change in that, because we are basing it largely on our own epidemiological experience.

Senator SIMPSON. And then, in your judgment, if we were to establish a system which compensated victims or individuals in one context where, in another context, an exposure of that same amount is within federally permitted limits, you do not see a confounding or confusion in there?

Dr. CATLIN. I cannot guess, Senator, exactly where this will come out in terms of what levels of probability of causation may be adopted for compensation determinations. But I do believe that, as was also pointed out yesterday, no level that is promulgated as a radiation protection standard grants an absolute degree of safety. And I do believe we have some exposure situations where an individual will certainly go higher than the 50-percent probability of causation, even under the present standards.

Senator SIMPSON. Well, I appreciate very much your views. I have some other questions, and perhaps Senator Hatch will. I hate to submit those in writing, yet I have no choice, if I want to extend the courtesy of being present to the other witnesses, and I regret that, but I must do that.

I thank you very much.

Our next panel consists of Mr. Vincent Boyer, senior vice president for nuclear power, Philadelphia Electric Co., Philadelphia, PA., and Samuel T. Fife, Atomic Trades & Labor Council, Oak Ridge, TN.

Good morning. I will appreciate, out of sheer necessity and nothing else, the necessity of your limiting your remarks to 5 minutes each, if you would, please.

Mr. Boyer, please.

STATEMENT OF VINCENT BOYER, SENIOR VICE PRESIDENT, PHILADELPHIA ELECTRIC CO., ACCOMPANIED BY JOYCE P. DAVIS, GENERAL PHYSICS CORPORATION; AND SAMUEL T. FIFE, CHIEF UNION STEWARD, ATOMIC TRADES AND LABOR COUNCIL, OAK RIDGE, TN

Mr. BOYER. Mr. Chairman, I am Vincent Boyer, senior vice president of Philadelphia Electric Co., and I have with me today, Joyce Davis, a certified health physicist and an attorney from General Physics Corp.

My testimony is provided on behalf of the Edison Electric Institute. The institute members currently have 75 nuclear powerplants with full power operating licenses and 20 more in the pipeline. Many thousands of workers are employed at our nuclear facilities, and they are exposed under strict controls to small amounts of low-level ionizing radiation above natural background levels during the normal course of their employment.

It is because of the exposure of these workers to low-level radiation that Edison Electric Institute is concerned about the development and possible use of the methodology described in the NIH report.

The information in the NIH report supports the conclusion that the risks of exposure to low-level radiation are quite small. The assumptions that went into developing the information and methodologies have been identified by the working group in is report. Some of these issues were discussed further in the report of the National Academy of Sciences Oversight Committee and in chapter 7 of their report, they looked into the possible use of PC methodology in claims adjudication.

All these issues—that is, the technical, legal, and social issues—deserve further review and comment not only by the scientific community, but by other concerned segments of the public, as well. The statutory mandated name that has been used for the methodology described in the NIH report, "Probability of Causation Tables," is, we believe, unfortunate, and should be changed to avoid misunderstanding. My prepared remarks contain further information pertaining to our concerns.

Furthermore, we do note that the NAS oversight committee also expressed its concern about the nomenclature. We suggest, therefore, that a term be used describing how the quantity is calculated, not how it might be interpreted and used. The so-called probability of causation is in essence the radiation exposure cancer risk divided by the total cancer risk calculated for a given set of statistical circumstances. Therefore, we believe a more scientifically descriptive and neutral name like, "risk quotient" or "risk ratio" would be appropriate.

It must be emphasized that the risk quotient methodology is not a scientific or automatic way of determining the complex issues of legal causation, liability, or compensation. It is still to be determined whether or when the risk quotient estimates calculated by these methods are appropriate for use as evidence in legal proceedings. In general, we believe that judges and lawyers should decide whether evidence on risk quotients is relevant and material to the causation question, or to any other issue in a particular case.

Edison Electric Institute believes it is vital for the integrity of science in our legal system that social and other policy considerations not be mixed with scientific ones in a PC compensation structure which could be misconstrued as a scientific method for solving an essentially social and political problem.

Thus, we urge that the NIH report be considered on its merits solely as a scientific document, not as an automatic compensation method or formula.

We are aware that there has been some discussion of possible establishment of an administrative claims system or changes to tort law that might afford a special status to evidence of risk quotient estimates generally and to the NIH report in particular.

EEI urges that legislators cautiously examine the implication of any such proposal which could ultimately influence our existing system of tort or workers' compensation law. It should also be considered that any system of compensation that bases its decision on statistical evidence only, in cases relating to identified individuals, that it involves an inherently arbitrary element.

With regard to Senator Hatch's current proposal for administrative system to provide compensation to persons claiming injury caused by atmospheric testing programs, EEI takes no position. It should be noted that the considerations relating to the radiation exposures received by the adult workers in the regulated commercial nuclear power program differ in many ways from the considerations involved in the weapons testing situation. And a system that might be appropriate for one situation would not necessarily be appropriate for the other.

We thank you for this opportunity.

I understand my full remarks will be included in the testimony.

Senator SIMPSON. Indeed, they will, and I appreciate your willingness to do that.

Thank you very much.

[The prepared statement of Mr. Boyer and responses to questions submitted by Senators Hatch and Simpson follow:]

STATEMENT BY
THE EDISON ELECTRIC INSTITUTE
BEFORE THE
JOINT HEARINGS OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
AND THE
SUBCOMMITTEE ON NUCLEAR REGULATION OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

JUNE 12, 1985

Mr. Chairman and Subcommittee members, my name is Vincent S. Boyer, I am a Senior Vice President of the Philadelphia Electric Company. With me today is Joyce P. Davis, from General Physics Corporation.

My testimony is provided on behalf of the Edison Electric Institute (EEI). EEI is the association of the nation's investor-owned electric utilities. Its members serve 96 percent of all customers served by the investor-owned segment of the industry. They generate approximately 75 percent of all electricity in the country and service 73 percent of all ultimate customers in the nation. In addition, its members currently have 75 nuclear power plants with full power operating licenses, three with low power licenses, and 24 more under construction. Many thousands of workers are employed at our nuclear facilities. Many of these workers may be exposed under strict controls to small amounts of low level ionizing radiation above natural background radiation during the normal course of their employment. It is because of the exposure of these workers to low level radiation that EEI is concerned about the development and possible use of the methodologies described in the NIH Report.

The mandate of Section 7(b) of the Orphan Drug Act is to present the best available scientific evidence on radiation exposure risks in a way that might be helpful to decision-makers. No specific application is mentioned in the statute. We believe that the NIH Group has acted properly and commend their effort in formulating and presenting the information in a way that does not pre-suppose its use in a particular forum or context. In evaluating the Report, the data and methodologies proffered should be considered free of pre-conceived ideas of how they are to be applied in practice. The information in the NIH report is, for the most part, based on the same data that have been used in the nuclear industry for prospective safety assessments, and supports the conclusion that the risks of exposure to low level radiation are quite small.

The assumptions that went into developing the information and methodologies have been identified by the Working Group in its Report. Some of these issues were discussed further in the Report of the National Academy of Sciences (NAS) Oversight Committee. Furthermore, in its Chapter VII, the Oversight Committee report ventured into the thicket of trans-scientific issues related to the possible use of the PC methodology in claims adjudication. All these issues, technical, legal, and social, deserve further review and comment, not only by the scientific community, but by other concerned segments of the public as well.

The statutorily mandated name that has been used for the methodology described in the NIH Report, "Probability of Causation Tables," is, we believe, unfortunate and should be changed to avoid misunderstanding. "Probability," besides being a somewhat ambiguous common term, is a specifically defined scientific concept. There is no generally recognized definition of "probability" as a legal term, and both the common and scientific usage may be found in legal proceedings. "Causation" is a term of art in tort law that carries implications beyond those of its scientific and common meanings. Use of the term "probability of causation" (PC) has aroused argument among scientists on whether the quantity calculated is a true mathematical "probability"*, and among lawyers on whether it adequately encompasses the complex concept of legal "causation." And, of course, as the lengthy report indicates, the approach used cannot be expressed in "Tables" alone.

As this Committee is aware, the NAS Oversight Committee also expressed its concern about the nomenclature. We believe the Academy's suggested alternative name, "assigned share for radiation as a cause of cancer," is equally unfortunate. Those words could be taken to imply that one individual's cancer involved many causative agents that could actually be "assigned" a "share" for each agent "causing" the cancer. We do not believe that such an implication was intended by the NAS Committee, nor is it in keeping with the statistical, rather than deterministic, nature of the methodology involved. Furthermore, such an interpretation, in the legal context, might be considered tantamount to a conclusive presumption of legal causation once exposure is shown.

---

* See page 40 of the NIH Task Group Report.

We suggest, therefore, that a term be used describing how the quantity is calculated, not how it might be interpreted in use. The so-called "probability of causation" is, in essence, the radiation exposure cancer risk divided by the total cancer risk, calculated for a given set of statistical circumstances. Therefore, we believe a more scientifically descriptive (and neutral) name, like "Risk Quotient" or "Risk Ratio" would be appropriate.

The Report of the NIH Group suggests methodologies for estimating the ratio of risks for a particular situation, based on data and assumptions presented in the Report. It must be emphasized that this risk quotient methodology is not a "scientific" or automatic way of determining the complex issues of legal causation, liability, or compensation. Rather, the NIH document provides a readily available compilation of existing epidemiological and statistical data, screened and evaluated by a group of recognized experts. It is still to be determined whether, or when, the risk quotient estimates calculated by these methods are appropriate for use as evidence in legal proceedings. In general, we believe that judges and lawyers should decide whether evidence on risk quotients is relevant and material to the causation question, or to any other issue, in a particular case. It should be recognized, however, that regardless of whether the NIH report is used in preparing evidence, many expert witnesses will reach their opinions on the issue of causation-in-fact based on an evaluation of existing data similar to the approach used by the NIH experts in their Report.

EEI believes it is vital for the integrity of science and our legal system that social and other policy considerations not be mixed with scientific ones in a "PC" compensation structure which could be misconstrued as a scientific method for solving an essentially social and political problem. Thus, we urge that the NIH Report be considered on its merits solely as a scientific document, not as an automatic compensation method or formula.

Other sets of risk quotient estimates already exist; they have been used as evidence in tort and workers' compensation cases by witnesses who testify as experts. These other estimates were not developed with the broad interaction of professionals from a variety of disciplines that characterizes the NIH Report. Therefore, risk quotients based on the NIH report certainly deserve more weight than the others.

We are aware that there has been some discussion of a possible establishment of an administrative claims system or changes to tort law that might afford a special status to evidence of risk quotient estimates generally, and to the NIH Report in particular. EEI urges that legislators cautiously examine the implications of any such proposal which could ultimately influence our existing system of tort or workers' compensation law. It should also be considered that any system of compensation that bases its decisions on statistical evidence only, in cases relating to identified individuals, involves an inherently arbitrary element. Such a system must be carefully designed to avoid infringing the constitutional right to due process of law.

With regard to Senator Hatch's current proposal for an administrative system to provide compensation to persons claiming injury caused by the atmospheric testing program, EEI takes no position. It should be noted that the considerations relating to the radiation exposures received by the adult workers in the regulated commercial nuclear power program differ in many ways from the considerations involved in the weapons testing situation: A system that might be appropriate for one situation would not necessarily be appropriate for the other.

We believe legislative action on any changes to the legal system should be deferred to allow time for further scientific peer review of the NIH Report, public comments, and policy studies on the usefulness of the risk quotient approach in the adjudication of claims, in light of the concerns raised by the Oversight Committee in Chapter VII of its Report.

The Edison Electric Institute appreciates the opportunity to provide these comments.

* * * *

6:7:85

RESPONSES BY MR. BOYER TO QUESTIONS FROM SENATOR HATCH

1. Mr. Boyer, to set your mind at rest, I don't know of anyone who is now planning to change the legal system legislatively on the basis of the NIH report. I agree entirely that more time and more discussion are needed before any such plans are contemplated. I do wonder why people are so squeemish about a methodology that everyone is essentially using. Why are people so reluctant to admit that "probabilities" are the only game in town. You say that you want judges and lawyers to decide whether evidence on probabilities of causation is relevant and material. Well, if it isn't, what else is?

A: To the extent that an expert witness uses the data and methodology in the NIH Tables as the basis for his opinion on the causation issue, we believe this evidence should be generally admissible in court cases where causation is an issue. However, that does not mean that the methods used or the results of the calculations should be incontestable. We do not think it appropriate, in tort cases, for the NIH document to be presented in a way that usurps the jury's role of making the ultimate determination, based on all the evidence, of whether it is more likely than not that the alleged injury was caused in fact by radiation. Such a decision is a judgmental, not a mathematical, determination. Thus, it is for the judge to decide the admissibility of this, or any other evidence.

2. Mr. Boyer, since Three Mile Island there have been no new plans for nuclear power plants, and the plans for a number of plants have been cancelled. Do you not think that the chaos in the courtrooms over things nuclear has something to do with this? Do you not think that some ballast is necessary in these considerations? Do you think that the nuclear industry can survive if nothing is produced to add some perspective to the nuclear debate in the courtrooms and elsewhere?

A: The situation with respect to new plants and cancellations is a complex one. It affects fossil as well as nuclear plants, and has several causes, the most significant of which is related to the much lower growth in the demand for electricity and the associated financial and economic impacts. However, it is certainly true that public misperceptions have complicated an already difficult situation. We welcome the NIH report as another scientific document that re-enforces our conviction of the safety of nuclear power plant operations. We would be pleased to see this report used to clarify issues relating to alleged radiation-induced illness in all forums. Our only concern is that the NIH report not be given a status that no current scientific work can claim--the definite determination of causation for every individual cancer. It remains a best estimate of the scientific community, based on statistical evidence that is as yet incomplete. While it may be the best that we have, it is far from perfect. In particular, as a statistically based work, it can only consider the statistically typical individual. Its relevance to an actual individual can always be questioned.

3. Mr. Boyer, both Dr. Lapp and Dr. Catlin have testified that the NIH methodology does not lead to undue liability on the part of the nuclear industry, that the expense would be manageable, and that no undue sense of the dangers of radiation would be promoted. Now, I realize that this testimony does not endear the tables to Mr. Fife, but I would think that your appreciation for them might be a bit warmer. Why are you so apprehensive about this NIH report?

A: Our apprehension stems from a lack of definition of the structure in which such a methodology is to be used. We have little concern about its use by an expert witness to support his opinion in a tort case. That is, in effect, similar to what is being done in such cases today. However, discussions about the use of the methodology often seem to presume it will be considered dispositive on the question of causation. That could mean that neither side could contest the methodology, the data used to prepare the NIH Tables or their applicability to a particular individual. If the NIH report were to be considered incontestable, the claimant and defendant would be giving up their rights to challenge it. In return the adjudication system must be set up to provide off-setting benfits for the claimant, e.g., a speedy decision or a relaxed burden of proof, and for the defendant, e.g., a limitation on liability, a sole remedy, or a final (non-appealable) determination.

We are also concerned that the Tables are sometimes proposed to be used to decide not only the causation question but also such issues as the degree of liability given causation, or the amount of compensation once liability has been shown. This, again, goes far beyond their use as mere evidence in tort trials. Before we can judge the reasonableness of such a compensation system, we need information on the proposed formula for determining compensation for each "causation" level, and other applicable decision rules.

RESPONSES BY MR. BOYER TO QUESTIONS FROM SENATOR SIMPSON

1. It has been suggested that if the Congress is going to legislate the use of the "probability of causation" methodology, it might consider using it as a basis for precluding the filing of claims that do not meet some minimum "PC" value. Please comment on that assertion.

A: The approach to screening claims seems a reasonable one for claims processed by administrative agencies and workers' compensation forums. It would help the decision-makers focus on claims that are most likely to have merit. Such a "screening" approach is less in keeping with the tort system, and it is not clear how the approach could be applied there.

2. Based upon your review of the tables, and the Oversight Committee's report, are the uncertainties that have been identified of sufficient magnitude to warrant additional scientific work, prior to using these tables as a basis for compensating individual cancer claimants, or do the tables have a sufficient degree of accuracy now to be able to apply them in this context?

A: It is true that major uncertainties remain in the scientific understanding of radiation carcinogenesis. Deterministic methods do not exist to allow actual causation to be decided with certainty. More scientific work is certainly warranted in this area. If decisions have to be made now in individual cases, they have to be made without perfect information. The NIH report uses the latest scientific data and the best methodologies that competent scientists can devise to estimate causation for typical individuals, since it can't be determined for actual individuals. If the Tables are not themselves applied in determining claims, then expert witnesses would apply similar data and methods to arrive at estimates. Otherwise, the claims would be decided on other than a scientifically-informed bases.

3. Please comment on your view of the potential impact of this methodology, if employed as a basis for compensation, on the way in which occupational radiation protection standards are established in this country.

A: The existence of the NIH Report, whether or not the methodology is directly used for deciding on compensation, should not affect the way in which occupational radiation standards are established at all. Since the same basic data are used in somewhat different ways for prospective (standards) and retrospective (claims) applications, there is no incompatibility between them.

4. Would a decision to compensate an individual for a given level of radiation exposure serve to undermine the approach that we have taken to radiation protection standards, where the Federal government may, indeed, have determined that such a dose was permissible?

A: As discussed above, there is no essential incompatibility between standards-setting and compensation decisions. It is recognized that the occupational standards are "safe" in comparison to other risks of life. They are not absolutely hazard-free, and therefore, some risk is involved. This means that in a large enough population of individuals exposed to radiation at or below "permissible doses", for example, a small number will contract radiation caused cancer, even though the prospective risk for each of them was very small. In that large population there will be many more naturally occuring cancers, which are clinically indistinguishable from those of radiogenic origin. The Federal Government recognized that radiation exposure carries this small risk when establishing the standards and determined that it was acceptable.

We recognize that, using the NIH methodology, a few persons in the population of those exposed who develop rare cancers may be categorized, statistically, as having risk quotients greater than 50%. Thus, a decision-maker might find it more likely than not that their cancers had been, in fact, caused by the radiation. However, whether the claimant would be compensated for the injury would also depend on other factors involved, e.g. determination of "legal" or "proximate" cause, findings of negligence, etc. It is our opinion that in the case where the exposure was within the federally established standard there would generally be no negligence, and thus the defendant in a tort suit would not be liable, regardless of the results on the causation question. It should be noted that for radiation at occupational levels the cases where the risk quotient turns out to be close to 50% will be rare. Thus, even in a forum where strict liability or related concepts apply (e.g., workers compensation) the number of successful claimants, and overall amount of compensation would be small, as long as the PC methodology were applied in a reasonable manner.

5. Have you undertaken a review of the "probability of causation" approach reflected in the Ad Hoc Group's report, and compared the results that you would reach applying this methodology to occupational exposures, versus the results that various courts and workmen's compensation boards have been reaching in radiation compensation cases?

A: EEI has not undertaken a specific comparison of the results of applying the risk quotient approach to the actual results of recent cases. It is our impression, however, that many of the cases in which compensation has been awarded would have shown extremely low values of the risk quotient.

Senator SIMPSON. And now, Mr. Fife, please.

Mr. FIFE. Thank you, Senator, for this opportunity to speak.

I would like to commend the ad hoc committee for taking the stand and making the statement that radiation does cause cancer.

As a worker at a DOE facility, I very seldom, or never, hear this statement from the Department of Energy people.

I am a chemical operating working with radioactive waste, isotope production, decontamination, and decommissioning at the Oak Ridge National Laboratory. I am also chief union steward for the International Chemical Workers Union, Local 715, health and safety representative for 18 bargaining units of the Atomic Trades and Labor Council, and in these positions, I represent nearly 4,400 hourly workers at the laboratory and at the Y-12 Nuclear Weapons Facility.

I am also here today representing 22,000 hourly employees of the National Atomic Labor Health and Safety Conference. This is a coalition of local unions and councils at eight DOE facilities nationwide, two international unions, and a department of the AFL-CIO.

I will not go through and list all the unions here, but just the facilities: Oak Ridge National Laboratory; Y-12 Nuclear Weapons Facility; Rocky Flats Plutonium Facility; Pantex Nuclear Weapons Facility; Bendix Plant, Kansas City; Fernald Feed Materials Plant, Fernald, OH; Machinists Local, Gaseous Diffusion Plant and Gas Centrifuge Plant, Piketon, OH; the International Chemical Workers Union; United Steel Workers of America, AFL-CIO's Metal Trades Department.

Also, as the only representative here, I will be speaking for the interests of 60,000 hourly workers at the DOE facilities, as well as 2 million radiation workers in this country who daily are exposed to radiation risk at the workplace.

I would also like to enter into the record that as a worker at these DOE facilities, I have been exposed to plutonium, cesium, strontium, and actinides, in which I now discharge in my urine at this time and have done so over the past 3 years.

I find it difficult to accept this committee's avoidance and refusal to consider this internal contamination. I have a personal interest, as well as the other radiation workers, as to what kind of compensation, or for that matter, what kind of cancers I may come down with in the future.

I know of individuals who have died of cancer, who now have cancer, and I am afraid, quite a few who may have cancer in the future. We are in an industry that is 40 years old this year. It is just coming of age, like many of the other industries that have been developed throughout the history. We are living with a material that has been developed by this Government, was necessary during a time of war, and we are now at the point where we are still seeing victims in these DOE facilities, even though we are not at war.

I would like to bring to your attention, in dealing with the dose-symmetry problems that come through DOE's lack of ability to keep track of dose—I, for instance, after being involved in an incident, requested my records and found out that my first piss sample that was turned in was conveniently lost. So they waited 2 or 3 weeks to give me an opportunity to piss off a little bit of the wonderful materials they supposedly have there, and then they take up another sample.

Nobody will tell me a definite reason as to why the sample was lost. This is just one example of—you know, how do I go to these tables and deal with them when I am depending on DOE and the Federal Government to provide my dose-symmetry records. It is something I am not capable of doing.

I also wonder why the ad hoc committee did not have anybody on their committee who would present the worker's situation, the guy who is out there, actually doing the work and is being exposed day by day.

I also bring to your attention the *Joe Harding* case that goes into court today in Paducah, KY, of a chemical operator who worked for 18 years in the facility. DOE claimed he had an exposure rate of 2R. He was given a medical disability retirement. Fifteen years after he retired, he had cancer. The man passed away. His bones were taken up and checked, and the dose that his bones displayed was 300R annually. And we are supposed to depend on these kinds of people and these kinds of goings on to give us an appropriate dose level?

Workers have the increased risk from exposure to external and internal radiation, and we also have the added risk of exposure to all types of chemicals and heavy metals in the workplace.

And I am going to be perfectly honest with you. I think we should be able to receive claims through the compensation system, through tort claims, but I also do not think that this Government should pay off on the various chemical carcinogenics that we are exposed to in the work. I think the chemical industry should stand up and be counted for their part, and not have the Government pay the whole bill. We have the normal industry exposures, and then we have the radiation thrown in on top of it.

I also find it difficult that the ad hoc committee did not have normal procedures for the peer review that I find the other scientific community demands, as for publishing and waiting to hear what the various people have to say regardless of whether they are in the mainstream or to the left or to the right; also, that the committee could not wait a period of time to find out what the revised A-bomb studies were going to be.

Also, we have been experiencing DOE's epidemiological studies of plant workers that have been going on in our facilities and in other facilities across the country, and DOE tries to underplay the real risks of low-level exposure in the workplace.

An example which is not covered in these tables is larynx cancer. I happen to know some individuals, approximately six of them, who were involved in an incident, and all these men came down with larynx cancer——

Senator SIMPSON. Mr. Fife, I regret—let me tell you what is happening now. We are having a rollcall vote. I have let you go 10 minutes instead of 5. You have a very compelling and powerful statement which you make, obviously. I must go and vote, and then I have a meeting with Senator Dole right after that.

Mr. FIFE. Then, sir, I would request that this committee consider having another day of hearings for the record.

Senator **Simpson**. Well, we would not have had, in any situation, regardless of that. Your testimony has been heard, and questions will be asked, so I doubt that that will be the case. I leave that to the judgment of Senator Hatch.

I can only tell you that what you describe is part of the issue here. If you were describing that to me as a man who practiced law for 18 years, well, let's toddle off to court, and we will do a number on somebody. That is the issue.

Mr. **Fife**. Yes, sir.

Senator **Simpson**. You have a compelling case, backed with those kinds of figures, and if your colleagues and your people in the workplace, your chums, your buddies—that is how you win lawsuits. That is what it is all about. That is the tort system. But the other parts we discuss here are the range areas that go back into low dosage, not people who work, and in every case, work intelligently in a situation which many of us would choose perhaps not to work in.

But enough of that. I have to go. But I am leaving the issue of further hearings solely to Senator Hatch. I would say that I will submit some questions to you in writing.

Mr. **Fife**. Please do.

Senator **Simpson**. I shall.

Thank you, Mr. Fife, and thank you, Mr. Boyer.

[The prepared statement of Mr. Fife and responses to questions submitted by Senators Hatch and Simpson follow:]

STATEMENT BY SAM FIFE

I. INTRODUCTION

My name is Sam Fife, from Oak Ridge, Tennessee. I am a chemical operator working with radioactive waste, isotope production reactors, decontamination, and decommissioning, at Oak Ridge National Laboratory.

I am the chief union steward for ICWU Local 715 and health and safety representative to our 18 union bargaining unit, the Atomic Trades and Labor Council. In these positions, I represent 4400 hourly workers at the lab and at Y-12 Nuclear Weapons Facility.

Today, I also represent approximately 22,000 hourly employees as the at this hearing for the National Atomic Labor Health and Safety Conference. Thi is a coalition of local unions and councils at 8 DOE facilities nationwide, 2 international unions, and a Department of the AFL-CIO. Included are:

- Atomic Trades and Labor Council representing 4400 hourly workers at the Y-12 Nuclear Weapons Facility and the Oak Ridge National Laboratory, Oak Ridge, TN
- USWA Local 8031 representing 3000 workers at the Rocky Flats Plutonium Facility, Golden, CO
- Amarillo Metal Trades Council representing 3000 workers at the Pantex Nuclear Weapons Facility near Amarillo, TX
- IAM Local 314 representing 4000 workers at the Bendix Plant, Kansas City, MO
- Fernald Atomic Trades and Labor Council representing 350 workers at the Fernald Feed Materials Plant, Fernald, OH
- IAM District 34, representing the FALTC IAM local, Fernald Feed Materials Plant, Fernald, OH, and the IAM local at the General Electric Plant, Cincinnati, OH
- OCAWU Local 3-689 representing 1400 hourly workers at Portsmouth Gaseous Diffusion Plant and Gas Centrifuge Plant, Piketon, OH
- International Chemical Workers Union (ICWU)
- United Steel Workers of America (USWA)

o AFL-CIO's Metal Trades Department

But because I am the only labor representative testifying at these hearings, I also represent the interests of the 60,000 hourly workers at all DOE facilities. There are also over 2 million radiation workers in this country who, daily, are exposed to radiation risks at the workplace. Labor's voice was absent from the November 1984 hearings on the draft of these tables; I was invited to testify today on short notice, only after the unions sent a letter insisting we be included. I feel like I speak for those two million as no one here can.

Our interests in testifying today are clear: We don't like the Radioepidemiological Risk Tables because they will not work--not for people exposed to alpha beta and gamma in fallout in the 1950s and 1960s, and not for workers exposed daily to alpha, beta, and gamma radiation at the workplace.

- The tables controversially underplay the risk of harm from radiation. The tables will keep people and their families from being justly compensated for their injuries. The tables will permit the government and industry to maintain higher plant allowable limits of radiation levels, since industry can look at the tables and take a calculated gamble on their liability.
- The tables take into account external gamma radiation only, and ignore the very important effect of internal exposure, gotten through ingestion or inhalation. There is also a significant knowledge of of external beta exposure; the effects of both of these types of exposures have been known for at least thirty to forty years. Why are they not included in the risk tables?

- There is also the problem of DOE's lack of technical ability to keep track of dose. Joe Harding, whose court case is being held today in Paducah, Kentucky, was a chemical operator at Paducah Gaseous Diffusion Plant. The DOE claimed we had an 18 year career dose of 2R. After dying, 15 years after he retired with a cancer disability, his bones alone showed a dose to his body of up to 300R annually. What does this say about accurate exposure records? All of our records and the calculations that the fallout victims depend on are kept by the DOE.
- Workers have the increased risk from exposure to external and internal radiation, but we also have the added-on risk of exposure to all types of chemicals and heavy metals in the workplace.
- The exposure risks computed in the talbes are from a one-time exposure. What about a worker's daily chronic low-level exposure?
- There has been no peer review of these tables within the scientific community.
- The data used by the Working Group relies primarily on the unrevised version of the A-Bomb survivor studies.
- There has been a recent controversy that our unions have experienced over DOE's epidemiological studies of plant workers. DOE has apparently under-played the real risks of low-level exposures in the workplace.
- The Committee should take into account "quality of life" in calculating risks.

We would also like to add, at this time, a statement in support of the proposal to utilize certain aspects of workers compensation law to effect a more equitable standard of causation and a more equitable burden of proof for claimants seeking relief. Enclosed is a copy of the proposed alternative language. We cannot stress strongly enought that a radical change in the way proof of causation is presented and the way the burden of proof falls is not needed at this time. Cases are just now having their real day in court.

Sincerely,

S T Fife

Samuel T. Fife
Health and Safety Representative

cc: Robert G. Keil
President

ATOMIC TRADES AND LABOR COUNCIL
AFFILIATED WITH METAL TRADES DEPARTMENT AFL-CIO
P. O. BOX 366
OAK RIDGE, TENNESSEE 37830

8 August 1985

Senator Orrin G. Hatch
Chair, Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Dear Senator Hatch:

Enclosed are my responses to yours and Senator Simpson's questions, received August 5, 1985:

ANSWERS TO QUESTIONS FROM SENATOR HATCH, FOR THE RECORD:

1. Yes, I think that the dose records for DOE workers are unreliable. In general this unreliability is caused by pervasive credibility problems that DOE and its predecessor agencies (AEC, ERDA) have created over their years of self regulation. First, we perceive a conflict of interest when DOE monitors and regulates itself for evidence of overexposures. They maintain the monitoring equipment and pay the investigative personnel. They do not allow any other federal or state agency to investigate. (NIOSH has been "allowed" to begin epidemiologic studies, based on DOE's dose records for workers, in two instances-- at Piketon and Fernald-- but only after long procedural battles culminating long after the health complaints arose)

Second, DOE retains complete control and custody of all dosimetry records for workers. According to DOE, DOE "owns" the worker exposure data. This creates several problems. As strange as it sounds, an individual worker's exposure records, both invivo and badge data are kept separate and apart from that worker's medical records. The first treating doctor, in most cases the company doctor, has no immediate access to the worker's exposure data. This can lead to potential radiation-induced symptoms being treated as "fatigue" and "the flu." This happened in the case of a Piketon worker who was exposed to high-enriched UF_6 (uranium hexaflouride). With her external counts still 18 times above plant allowable limits, she was diagnosed as having the flue because she was nauseous, with a low-blood count, and continued low grade fever. After union demands, she was also monitored, one week after the accident on DOE's Oak Ridge mobile whole body counter at Fernald Plant and found to be "below background" for uranium-- this was while her external counts were still very high and her urine count was still measuring contamination. There has been an investigation of this involving a comparison of the Oak Ridge whole body counter with that of Argonne National Lab. A definite descrepancy was found and, as far as we know, further investigations mandated.

To get his own exposure record, the worker must file what amounts to a freedom of information access request; waiting up to 60 days for the data. When the worker receives the exposure data, he may find some dates on the exposure history marked "SNP" (sample not processable). In my case, I filed for my data and waited 90 days to receive it. The information on radioactive material in my urine after a large exposure was marked SNP. This is all I have to rely on in the event I contract cancer twenty years down the road-- piss samples taken days and weeks after the incident with the most important sample not processable. Enclosed are my own exposure records illustrating this incident I described.

2. I see this NIH report causing alot of confusion in use, so much so that it would override any benefit in the tables use. In short, I see it as a technical document that would be likely to be taken at face value, i.e., "its in the NIH report, so it must be true," by most who would be called on to use it in arbitration. Besides its confusing technical nature, the report is also plagued with a conflicting Congressional hearing record on its worth and bias in choice of the working group scientists. This long-winded technical "solution" also tends realistically, to disadvantage those less able to employ unlimited technical and legal help, while giving the upper hand to those with relatively unlimited resources. In our experience, the government is normally the defendent, or their indemified contractor, and is very interested in "precedent" and willing to spend hundreds of thousands of dollars to win a single case that would actually cost them less than half of what they spend. We see them using these tables to their advantage. We are aware that in the testimony of the Justice Department and the nuclear industry representatives, they feel like plantiffs will win cases and make money hand over fist using these tables, but they feel that way because they don't like to allow any presumptions in favor of the plantiff regarding radiation and cancer. They feel like they've got a good thing in the courts now. We think like them in one respect-- we believe the courts should continue to try cases without the tables or the NIH report to confuse things, because we think that, as the industry "comes of age"-- over 40 years old now-- more and more independent medical evidence will show complete causal connections between radiation and cancer. These tables haver inherant problems and on confuse the issue.

3. (No question three on the original sent me).

4. I think that the NIH report underplays the risks of radiation because of a perceived conflict of interest regarding the scientific working group. At the very least, your committee should have known that to appear to be biased causes as much trouble as the actual bias. Sometimes we the workers have no scientific education equal to government scientists, but we do experience self-interested behaviour from DOE and the company on a daily basis. We do see the majority of scientists in government called in to testify by government lawyers to testify against workers, veterans and downwinders in these radiation related court trials. We have seen outright deceit on the part of DOE take place regarding the worker health and mortality studies which were contracted and paid for by the DOE. We know that people grow older, get cancer and die of it. Nuclear workers just do it in greater numbers. The numbers that we see die in our plant experience are not reflected in the DOE paid-for epidemiology studies.

For one thing, those studies count in clerical workers, and many others who do not work around hazardous materials. They do not do the most commonsense thing which is to study discrete work areas or crews and see what happens to people who work in the same area over time. Instead they study a cohort group of white males plant-wide-- including managers, office workers, parking lot attendants, as well as the 20% or so of workers who work around radiation. I know of a reactor work crew, all 6 of whom were in a recorded "incident." ALL 6 DEVELOPED LARNYX CANCER AND HAD THEIR LARNYXS REMOVED. That group of men were never studied or showed up in the larger studies as an abnormality.

QUESTIONS OF SENATOR ALAN K. SIMPSON, FOR THE RECORD

FOR SAMUEL FIFE

1. It has been suggested that if the Congress is going to legislate the use of the "probability of causation" methodology, it might consider using it as a basis for precluding the filing of claims that do not meet some minimum "PC" value. Please comment on that assertion.

2. Based upon your review of the tables, and the Oversight Committee's report, are the uncertainties that have been identified of sufficient magnitude to warrant additional scientific work, prior to using these tables as a basis for compensating individual cancer claimants, or do the tables have a sufficient degree of accuracy now to be able to apply them in this context?

3. Please comment on your view of the potential impact of this methodology, if employed as a basis for compensation, on the way in which occupational radiation protection standards are established in this country.

4. Would a decision to compensate an individual for a given level of radiation exposure serve to undermine the approach that we have taken to radiation protection standards, where the Federal government may, indeed, have determined that such a dose was permissible?

5. Have you undertaken a review of the "probability of causation" approach reflected in the Ad Hoc Group's report, and compared the results that you would reach applying this methodology to occupational exposures, versus the results that various courts and workmen's compensation boards have been reaching in radiation compensation cases?

ANSWERS TO QUESTIONS FROM SENATOR SIMPSON, FOR THE RECORD.

1. If that assertion were to become practice, according to our assessment of these risk tables, the threshold for bringing a radiation injury claim would be so artificially high that it would, in effect, obstruct the true reasons for having courts try these cases--to determine truth. The issues involved in these potential cases are presently too controversial to "codify" them in PC tables, especially such as these. Let our judicial system work on it unhampered for awhile.

2. Whether the tables in question do or do not have a sufficient degree of accuracy is unknowable. The important thing is, if you want tables like these to deal with radiation litigation, to make them acceptable to people who will have to use them. The Committee has done a very poor job in planning for this acceptance. The tables will be more readily acceptable if there is an independent scientific review of them. By independent scientists, we mean scientists who do not get most of their grants and salaries from the federal government, the primary and ultimate defendant in these lawsuits, and who have not testified for the defense in these still active litigations. To have left these independents out of the working group is to have asked for all the controversy you have now, from the very people this legislation is supposed to "help".

3. Occupational radiation protection standards are formulated under the rhetoric "as low as reasonably achievable" (ALARA). It is hard to speculate on how much effect these PC tables would have on the setting of standards, if, in fact, the goal of radiation protection standards, i.e., absolute safety, is one whose explicit parameters are financial feasibility and technological possibility. Standard-setting bodies, both international and national, are unofficial and formally unaccountable (except within the confines of professional ethics). Historically, they have been composed primarily of nuclear industry representatives. We also know that, as in other hazardous industry such as asbestos, cotton, and coal where much of the health costs are externalized for a long time, it takes much pressure and political action before lives (including the "quality of lives") are put above pure profits. Industry reps have an absolut interest in making the industry safer in order to insure low legal liability. They also have no incentive to improve situations for which they won't be held liable.

We can speculate on how the methodologies reflected in these tables will affect how the standards are applied. These PC tables, by making industry liable for only a portion of what radiation can potentially cause, will set industry's collective eye at a much lower order of safety. It is not hard to visualize that, with an eye on stockholder interests and with no liability incentive, companies (and the DOE, for they are an "owner" in this instance) could decide to expose older workers to a higher amount than ALARA would dictate simply because they can, under the existing regulations, and because it would not be likely that a 40 year-old, exposed to x amount of radiation, would, by PC table truth, have a cancer caused by his or her work. It would simply be a case of "growing old, getting cancer, and dying."

-over-

(Question 3. continued)

We can also speculate that, because these tables do not even begin to address internal contamination from alpha and beta particles--by far the greatest and most common occupational radiation risk, that industry/government would distort this lack to mean "lack of risk." The tables also do not deal with the many chemical hazards associated with radiohazards. These risks from the chemical properties of various radioactive substances go hand in hand with radiation risks when trying to determine PC values of a cancer caused by that material. This especially relates to long-term chronic cancer exposure (as opposed to a one-shot exposure from weapons test fallout).

4. No, a decision to compensate an occupationally exposed individual using the PC tables, even as they exist now, would not undermine the "permissible dose" standards upon which the federal regulations are built. The regulatory concept is and has been since Dr. Karl Morgan suggested it in 1947, "maximum permissible dose." That is a concept with the reality of technical and financial feasibility in mind like "ALARA" mentioned above. It is also a term that under Dr. Morgan's leadership sought to do away with the false notion of a "tolerance dose " implying that there was a "safe" dose or one that was tolerable. A permissible dose of radiation is by no one's statement of a safe dose. The concept adopted by all standard setting bodies is that no dose is presumed safe. This argument should not be used to bolster the case for these PC tables because, as stated earlier, we think that the judicial fact-finding system should be allowed to work along by itself for awhile without being confused by these tables.

5. We have not undertaken such review. It is an excellent idea bu one on which it is hard to obtain data. Most potential workers comp suits on radiation claims, whether brought before an administrative board or a court, are settled before adjudication, usually with full award paid to the plantiff by way of settlement. Most settlement agreements forbid parties to talk about the case or settlement contract. If not for some unions keeping records on members settlements we would not even know this much. We do know that the nuclear industry, like the asbestos industry and the coal industry acts to avoid costs by not allowing "bad" precedents to be set. This is part of the problem in conducting a survey such as you suggest.

Senator SIMPSON. Perhaps at this point, then, I can seat the final panel and let them proceed, and then I will go vote, and the staff will receive the balance of the testimony from the final two witnesses.

Now we have Richard Schmalz, American Nuclear Insurers, Southington, CT, and Dr. Joseph Fiksel, Arthur D. Little, Inc., Massachusetts.

And let me ask you, and I really regret doing this, but I have no choice, if you would proceed with your testimony and limit that to 5 minutes each. I am going to go vote in just a few minutes, and then I will try desperately to return here to hear the balance of your testimony and make a further inquiry with some questions, if I may.

Mr. SCHMALZ. Senator, I am going to ask Dr. Fiksel to testify first, if I could, while you are still here.

Senator SIMPSON. Hurry up. I am going to disappear swiftly.

STATEMENT OF DR. JOSEPH FIKSEL, MANAGER, DECISION AND RISK MANAGEMENT, ARTHUR D. LITTLE, MASSACHUSETTS, AND RICHARD SCHMALZ, COUNSEL, AMERICAN NUCLEAR INSURERS

Dr. FIKSEL. Senator, with your indulgence, I will try to keep my comments to about 3 minutes or so. We have submitted a statement for the record, and we will also submit a full report for the record.

Senator SIMPSON. Thank you.

Dr. FIKSEL. We have been studying the question of uncertainty in the PC tables, and we do feel the uncertainties are considerably larger than were reported by the working group.

The first thing I want to say is we do feel that the working group made their best efforts. We feel that the problem here is simply an immense uncertainty and a lack of sufficient scientific data to produce probability of causation estimates. In fact, it so happens that it is not possible to calculate a probability of causation for cancer, because of the fact that cancer is a multifactorial disease. In other words, it is a result of many different things. It is a result of genetic susceptibility, diet, lifestyle, and other factors. So that in fact, there is no such thing as a probability of causation for cancer.

The formula that has been presented is not a scientific probability. It is simply the ratio of the excess incidence of cancer to the total incidence of cancer, and those are estimates which were created in the face of a great deal of uncertainty.

I would like to illustrate the kinds of uncertainties that we are talking about.

Yesterday, we heard Dr. Jablon say that a PC of 5 percent would have an uncertainty range of between about 3½ percent to 9 percent. Our analysis—and, based not on subjective estimates, as the working group did, but based upon a fairly straight-forward statistical analysis—shows that due only to the sampling variability—in other words, only due to limitations on sample size—the variability could be as much as anywhere from below zero up to 38 percent for a PC of 5 percent: and that the propagation of error—in other words, the presence of uncertainty in the risk estimates—will induce an uncertainty range for a PC of 5 percent of anywhere between below zero up to about 53 percent. This is just an example, and we have calculated ranges for the other PC's that have been advanced by the working group.

I would propose to you that the working group's statistical estimates of uncertainty have not been reviewed by the oversight committee. In fact, they were prepared very recently and have not undergone any independent scrutiny. And I would say do not take our word for it. Have someone review carefully those uncertainty estimates. We feel there are many sources of uncertainty that have not been accounted for, and one of the most important that was not accounted for is what was mentioned earlier by Mr. Willmore of the Justice Department; namely, the heterogeneity of human populations, the fact that there is no such thing as a typical individual, and therefore, that the actual susceptibility of individuals in a population can vary tremendously. This source of uncertainty was not even accounted for in the working group's estimates.

I think I will stop here, Senator, in case you do have any questions.

Senator SIMPSON. I do, but I would ask Mr. Schmalz if you wish to testify while I am here, and I must go. I regret that, but I must.

[The prepared statement of Dr. Fiksel and responses to questions submitted by Senator Hatch follows:]

STATEMENT OF

JOSEPH FIKSEL, PH.D.
ARTHUR D. LITTLE, INC.

BEFORE THE COMMITTEE ON
LABOR AND HUMAN RESOURCES
AND
THE SUBCOMMITTEE ON NUCLEAR REGULATION
OF THE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

UNITED STATES SENATE
JUNE 12, 1985

My name is Joseph Fiksel, and I am Manager of Decision and Risk Management at Arthur D. Little, Inc. For over two years we have been studying the theoretical and practical issues surrounding probability of causation, in the context of radiogenic cancers. My colleague, Tony Cox, has published an important paper examining the statistical foundations of risk attribution, and is continuing his research on this subject at M.I.T. Part of my testimony is based on a report prepared for American Nuclear Insurers and Mutual Atomic Energy Liability Underwriters, in which we investigate the uncertainties in the probability of causation (PC) method. The full report will be submitted for the record.

The principal focus of my remarks will be on both the scientific and practical limitations of the proposed PC method. We can characterize the NIH Working Group's efforts as essentially consisting of two parts: The development of cancer incidence estimates for various classes of human populations, and the development of a formula which uses those data to assign a relative share of the risk to radiation. In spite of the difficulties of estimating low-level radiation risks, the Working Group has assembled an impressive array of cancer incidence projections, using the best available scientific knowledge. However, the development of the so-called PC formula was much more challenging than originally anticipated, and serious concerns remain about its applicability.

At the outset I would like to clarify that my main purpose in critiquing the substantial efforts of the NIH Working Group is to clarify the difficulty of trying to attribute shares of causation using scientific formulae. The Working Group was assigned what has turned out to be an impossible task — calculating the probability that an individual's cancer was caused by radiation. It soon became evident that a true probability could not be calculated, because cancer is believed to result from the complex interaction of many factors. It is not meaningful to speak of a single cause, let alone to quantify the probability of causation.

However, the law required that PC tables be constructed, and the Working Group was obliged to make several compromises in order to produce the desired product. Instead of trying to calculate probabilities, they devised an approach based on estimating the excess incidence of cancer due to radiation exposure as a percentage of the total incidence. The Oversight Committee calls this an "assigned share", however we feel that a more appropriate nomenclature might be "risk ratio" or some other value-free term.

While terminology is important, there are also substantive questions to be addressed: Can the use of a PC formula provide a meaningful tool for consideration of individual claims? What criteria should be applied in reviewing the merits of this approach? At the previous hearings last September, I provided testimony regarding the conceptual shortcomings of this approach, and I will not dwell on those issues today. Suffice it to say that this risk ratio is not a probability, but simply a mathematical construct that appears intuitively reasonable. In fact, there are several alternative formulae that have been proposed, all equally reasonable on the surface. Upon closer inspection, however, all of these formulae exhibit important shortcomings.

For example, there are several aspects of the PC formula selected by the Working Group which raise concerns about its application to compensation. To circumvent the lack of adequate data about the interactions of radiation with other factors, including diet, lifestyle, genetic, and hormonal factors, the Working Group has used a multiplicative interaction model, which assumes that the relative excess risk due to radiation is independent of other factors that may be present. Not only is this assumption arbitrary, but it may bias the results by implicitly assigning to radiation all of the excess risk due to interactions between radiation and other factors. Moreover, the proposed approach ignores the heterogeneous nature of the -human populations to which the formula might be applied, introducing a large and unavoidable uncertainty into the results. I will return to this issue in a moment.

The key point is that there is no one scientifically "correct" formula, nor is a valid probability formula possible in the context of human cancer causation. Rather, the choice of a formula is a policy decision, and it should be evaluated according to policy-based criteria. For example, will the formula produce reliable and consistent results when applied to individuals? Our study reveals serious concerns about the usefulness of this formula due to the large uncertainties inherent in the approach.

There are several sources of uncertainty that enter into the PC calculation, and their combined impact, though difficult to quantify accurately, appears to be substantial. The three broad categories of uncertainty addressed are sampling variability, propagation of error, and population non-homogeneity.

Sampling variability

Sampling variability is the uncertainty that results from limitations on the sample sizes used in estimating human cancer incidence, particularly for low-frequency effects. This source of uncertainty alone implies a 95% confidence interval that varies by at least 10% in either direction, for PC estimates in the range of interest. In fact, for certain cancer sites, the variability may imply that an estimated PC of 30% would not be detectably different from zero at 95% confidence.

Propagation of error

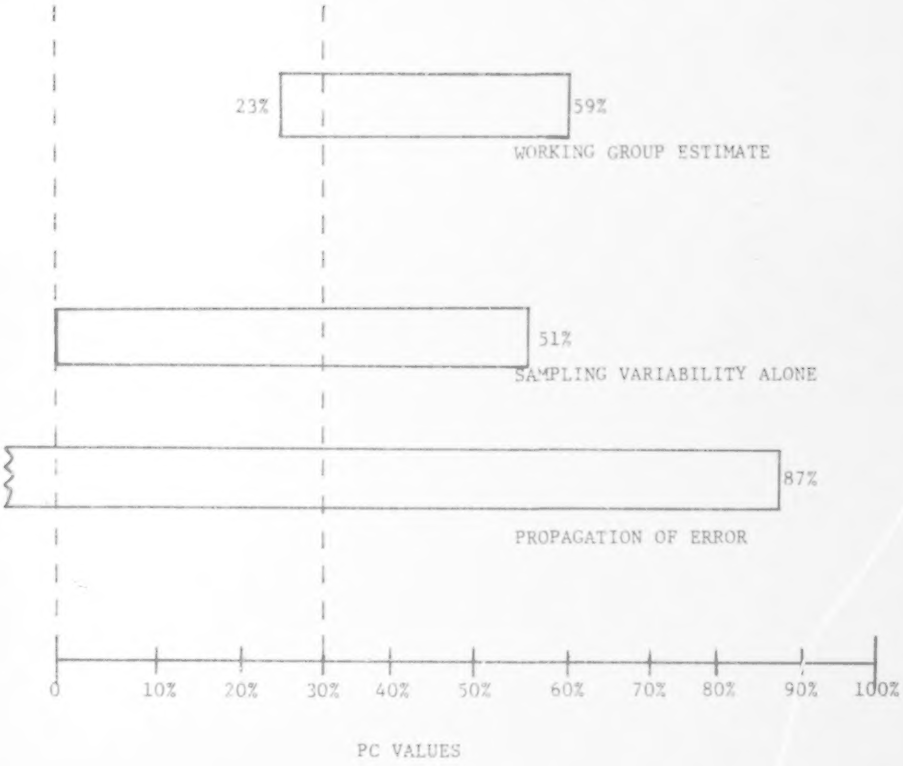
In addition, there is inherent variability, or error, in the estimation of hazard rates for cancer at different dose levels. This includes both modelling and data uncertainties due to a number of methodological limitations identified by the Working Group, including dose-response extrapolation, exposure estimation, and other issues. For example, this PC methodology applies only to discrete doses of radiation, like those from the atomic bomb, whereas typical radiation exposure is a low-level, continuous phenomenon. When the uncertain hazard rates are inserted into the PC formula, the propagated error is further magnified, and moreover a statistical bias is introduced. Plausible examples exist in which the confidence range due to propagation of error alone spans the interval from 0 to 90%, raising concern over the use of point estimates for assigning blame to radiation.

Population non-homogeneity

Finally, the most important source of uncertainty in the PC approach is the diversity, or non-homogeneity, of human populations. The aggregation of cancer data into broad classes based on sex and age, while necessary for purposes of estimation, ignores the variability of hazard rates within the population due to the genetic, lifestyle, and other factors mentioned earlier. In effect, the PC will differ widely among different members of the population. As a result, the hazard rate for a class is an artifact of aggregation that may have little or no relevance to the rates for specific individuals within that class; this was referred to by the Oversight Committee as the "partitioning problem". No amount of additional data collection or analysis can reduce this fundamental uncertainty.

Our evaluation of the above sources of uncertainty indicates that the errors in the PC estimates will be considerably larger than those subjectively estimated by the Working Group. It appears that in most applications to individual cases, for calculated PC values between 10% and 30%, the range of uncertainty would be so wide as to make any attribution of blame to radiation statistically unreliable. (See attached diagram.) This reflects fundamental limitations in the sciences of biology and epidemiology which will not easily be overcome in the foreseeable future. Consequently, the use of a formula-based assigned share approach does not appear to be suitable for purposes of distinguishing between individual compensation claims or allocating compensation to individual claimants.

COMPARISON OF TYPICAL UNCERTAINTY
INTERVALS FOR A 30% PC ESTIMATE



QUESTIONS FOR DR. FIKSEL FROM SENATOR HATCH:

1. Dr. Fiksel, I am in no position to engage you in a scientific debate. I am not a scientist, and my job here is not to debate you on points of science. I note, however, that your views were well known by both the NIH committee and the NAS committee and were rejected by both of these committees. It has been suggested that your plaint has more to do with insurance philosophy than with the science behind the tables or the question that tables are meant to address, which is, given people as they are and as they live, what additional risk comes from the introduction of radiation? When parties other than an insurers' client share responsibility with that client for damages, it is only natural that the insurer would try to have these other parties pay their share. Or, perhaps the insurer would try to get off the hook altogether by claiming the other parties bore a greater responsibility than the client. Now, every event has multiple causes in the sense that every event depends upon circumstances as well as a protagonist, and it is an easy thing to switch the protagonist and the circumstances. Does a car go down the road because there is an engine, or because there is gas in the tank or because a driver has decided to drive down the road? It might be that radiation causes cancer only in people who eat asparagus, and that asparagus contributes as much or more to the carcinogenisis than the radiation. Still, "but for" the radiation, the increased probability of the disease reflected in the probability of causation would not be manifested. For the purposes of liability, I don't know that the country cares just what radiation interacts with to achieve cancer. Your point might be more impressive if the tables implied that radiation was wildly dangerous, or if the tables showed vast numbers of people to have large probabilities of causation. But this does not seem to be the case. We seem to be talking about relatively few people with relatively rare cancers. Have I understood your point on "multiple causation" correctly; is this what you are getting at, the problem of shared liability?

Reply from Dr. Fiksel and Mr. Cox to Senator Hatch's Questions

Senator, we appreciate your efforts to understand the statistical questions underlying the "probability of causation" calculations. We have raised two major points: that the PC formula used by the Ad Hoc Working Group does not give correct expressions for probability of causation, and that the uncertainty about the numbers that the formula produces, if evaluated using objective statistical principles, is so great as to preclude useful application of the formula. Specifically, a realistic assessment of the uncertainties involved suggests that even calculated PC's as high as eighty percent (or as low as -80%) fail to provide significant evidence that the true PC for an individual differs from zero. The link between calculated and true PC's is simply too weak to support confident inference in applications to individual cases.

The Oversight Committee only recommended, but did not itself undertake, an assessment of the uncertainties involved in the PC tables. The Ad Hoc Working Group performed a somewhat subjective assessment from which many sources of uncertainty were excluded, and arrived at uncertainty estimates that we believe to be severely understated.

Both groups appear to have been aware of our views concerning the incorrectness of the PC formula. Since neither group has had the opportunity to address our points regarding the statistical precision and consequent practical usefulness of the PC numbers, we will confine the remainder of our remarks to the incorrectness of the formula.

The Oversight Committee, in contrast to the suggestion in your question to us, either accepted or independently developed our principal conclusions: that the PC tables do not give probabilities of causation, and that the numbers tabulated, rather than reflecting a purely objective, scientific calculation, implicitly make many social and policy judgements. These points are brought out on Pages 26 to 32 of the Oversight Committee's report.

Where we differ from the Oversight Committee is in their assertion (p. 31) that "Even though the number computed is not a probability, it is a reasonable way to apportion blame...". We agree that the formula does not in general produce probabilities. But we do not agree that the formula is a reasonable way to assign blame.

Our concerns are not related to insurance philosophy (or, for that matter, to insurance science). They are not even primarily related to the unarticulated philosophy behind the PC tables, or to the incomplete medical and epidemiological science that the table's creators were trying to encapsulate in the PC numbers. Rather, we are concerned that highly uncertain estimates are being fed into an incorrect formula, and being proposed for a use — inferences about individual cases — that violates sound statistical practice and risk accounting principles.

Like you, Senator, we are solely concerned with the "additional risk that comes from the introduction of radiation." However, we recognize that when risks are not additive, such allegedly "additional" risks must be carefully defined. Treating nonadditive risks by simple addition and subtraction leads to logical difficulties, as we have pointed out in journal articles and discussed with our professional colleagues in a number of forums. These logical difficulties are inherited by the proposed PC formula.

We are not concerned with invidious comparisons between the sizes of shares due to different sources. Indeed, we care about the shares allocated to other sources, whether asparagus or cigarette smoking, only because an incorrect accounting of these other shares necessarily implies an incorrect accounting of the remaining share that is attributed to radiation. Our concern is that this share not be miscalculated using an incorrect formula, and that the miscalculated values not then be printed in tables disseminated for public use under a misleading interpretation.

That the tables are dangerously misleading can be seen by example. In your own question, you noted that were it not for the radiation "the increased probability of the disease reflected in the probability of causation would not be manifested." But, in fact, a large portion of the increase in risk over base line now being attributed to radiation might still remain even if the radiation were removed, depending on what other factors were present. This is the very sort of discrepancy that makes the PC formula unreliable as a basis for policy decisions.

If not the country, at least a number of professional risk analysts care that interaction effects between radiation and other factors be correctly accounted for in apportioning cancer risks, so as to prevent provably incorrect assessments and risk accounting formulas from being adopted and promulgated by the Congress for practical use. Even if the current tables only rarely indicate large probabilities of causation, this does not seem to us to be reason to accept them as a sound or useful application of risk accounting.

We appreciate your patience in listening to our objections, and your willingness to consider the deficiencies of a methodology that so much time and effort have already been invested in. We urge that the asserted "reasonableness" of the current formula as a method of risk attribution be carefully reviewed by an independent, statistically knowledgable, party -- perhaps a political economist, rather than a medical scientist. We suggest that the uncertainty and precision of estimates associated with these or future tables be evaluated on purely statistical grounds by an independent statistician. In conclusion, we believe that the PC tables and statistical methodology as they now stand are not ready for release, and that any use of them in individual cases would not be supported by sound statistical or risk accounting principles.

Mr. SCHMALZ. Let me just make a very few brief remarks, Senator.

Insurers worldwide naturally share a deep interest in any proposal that could substantially change the ground rules for the payment of damages or compensation under the tort system or the workers' compensation system. These systems, as you know, have been under great pressure to pay more people more money than ever before, and there is dissatisfaction with the system that does not automatically respond to every claim.

While we applaud the scientific effort here to get the thorny question of when is a cancer caused by a dose of radiation, we do believe, as Dr. Fiksel has said, that the science is not sufficiently mature to make it useful for using it as a determinant in deriving compensation payments under the tort system or the workers' compensation system.

Senator SIMPSON. Let me say this, Mr. Schmalz. I must go now, but I want you to know the issue you address is a common one to the Superfund legislation, and we are pursuing that carefully in the Environment and Public Works Committee, that issue of insurability and that type of thing. So, let me submit my questions in writing to you, and they will be along the lines of compensation standards, overcompensation, undercompensation, whether the burden of proof on the defendant in the *Allen* case is something you see spreading in judicial circles, and the logic of those things. And, we will look at the issue of an additional hearing, and Senator Hatch and I will discuss that, and the staff members perhaps, but that is something that he has gone into rather exhaustively. I have just joined him for this series. I see the staff quaking there, as I suggest that, shaking visibly—because they have worked very hard in putting that together.

But I must go. I thank you. I hate to be discourteous, but I must cast my vote. They pay me for that.

Thank you very much.

Mr. SCHMALZ. Thank you, and we would be very pleased to answer any questions that you might submit in writing.

STAFF. Why don't you proceed with the balance of the testimony?

Mr. SCHMALZ. To follow up where we left off, the tort system and the workers' compensation system are under great pressure to pay more injured persons and in higher amounts than ever before. This increasingly heavy burden must be funded by private individuals or firms who look mainly to private insurers to spread and limit the risk. And of course ultimately, consumers must pay more for the goods or services they require.

The insurance market acts as a barometer in gauging the impact of the expansion and tort remedies. When worldwide insurance markets retreat or nearly vanish, as they have in the case of many products and medical specialties, and for environmental protection, it is a clear sign that our compensation system itself is becoming unpredictable.

The fundamental principle governing tort compensation has been that full compensation, regardless of need, regardless of the existence of collateral sources of benefits, is paid when there is fault, and there is a fairly strong proof of causal connection between the fault and the injury. We would note, however, that the strength of the proof is not nearly as high as is usually required by scientists for recognizing valid causal laws. The proof required in tort cases is merely more probably than not, or slightly more than 50 percent.

The radioepidemiological tables that are the subject of this hearing bear directly on this crucial matter of the causal connection between misconduct on the one hand and injury actually caused by such misconduct to a specific individual on the other. The tables have been prepared and reviewed by respected scientists, and they have been subjected to independent review by other experts. We have no doubt that the tables represent the best guidance that science can give on the basis of present knowledge.

But the question is not whether the scientists have done the best that can be done, but whether the tables themselves, or the method by which they were produced are useful for applying our present tort and workers' compensation systems to radiation injuries, or for modifying the assistance, or indeed, for designing new, general purpose, privately funded compensation systems.

This much larger question is of course not totally a scientific matter. The scientists who prepared and reviewed the tables do not purport to advise how the tables were to be used for these purposes. And we cite some statements in the ad hoc working group's report, and in the oversight committee's report, that indicate that all the scientists recognize great uncertainty in the tables that arise essentially from applying rough models to poorly understood biological processes with very little hard data.

The oversight committee recommended further quantitative appraisal. Their own limited investigation showed that the true assigned share could range from 85 to 5 percent. The oversight committee points out that the use of single numbers in the tables, as required by the Orphan Drug Act, rather than ranges, tends to cloud reality, but to avoid discussion of uncertainties in a quantitative fashion may suggest to nonscientists an unrealistically high precision of scientific knowledge—this is quoting from the oversight committee's report. The mere existence of tabulations of assigned shares, especially without accompanying quantitative expressions of their uncertainty, could stimulate unintended uses, scientific or otherwise, that would be inappropriate given the actual state of uncertainty. We, too, share some concern about the use of the term, "probability of causation." It is misleading. Dr. Fiksel has commented in his report on that, and the last panel also commented on it.

The oversight committee substituted the name "assigned share." However, this too seems equally misleading, because it embodies a nonscientific value judgment.

The oversight committee correctly explains that "assigned share" is not a unique property of an individual, but is rather the estimated excess cancer ratio of a group of which the individual is a member. This ratio is then assigned to each member of the group as a proxy for the individual's true probability of causation, which cannot be ascertained. The ratio is chameleon-like; its numerical value depends on the choice of the subgroup to which the individual is assigned.

We heard testimony yesterday and today that there is a great dispute about the preparation of the tables, and we too can note that if an assigned share depends on a subjective partition and represents the average of a group that is not homogeneous, it may not seem very reasonable or very scientific to those individuals whose compensation is less than what they believe they are entitled to. Insurers recognize this as similar to the problem they face in developing and applying rating classifications for automobile insurance. Those who live in the suburbs can only favor the classification system, while those who live in the cities do not. Insurers have encountered widespread claims of unfairness using a classification system analagous to that used to derive "assigned shares" even when they have an abundance of statistical data supporting not only the average subgroup probabilities, but also their homogeneity. Similar supporting data are not available for the radioepidemiological tables.

And if the "assigned share" is determined by a method that can substantially overstate the true individual probability or excess risk ratio, by propagating potential errors from sources so numerous and troublesome as the oversight committee suggests to be present, then those who initially must foot the bill will also find it hard to agree that it is scientific or reasonable. If the errors were random and tended to cancel each other, that would be helpful. But insurers believe that bias is a real problem in administering compensation systems. They are invariably construed liberally in favor of the individual for the simple reason that the amount of compensation to be paid the individual is relatively small in relation to the total pool of funds available to pay compensation. The latter amount is frequently regarded as unlimited in general purpose compensation systems such as the tort law or workers' compensation systems. But of course, if all doubts are resolved in favor of compensation in every individual case, then the aggregate compensation paid on the assigned share basis will substantially exceed that which might be computed on a less ambitious group basis or under the present tort system.

The redesign of compensation systems, or the design of new systems, particularly if they are to be funded by private means, is a more complex task than perhaps the epidemiologists realize, although the oversight committee's report does contain a brief discussion of several relevant points. There are, however, certain fundamentals that need careful consideration. Goals must be set and justified. Compensation levels must be consistent with the goals. And the system must be reasonably efficient in implementing the goals as compared with other possible means.

The tables themselves, in our view, represent a first step in a process that needs a great deal of attention, not only by epidemiologists, but also by scholars working in the fields of economics, law, and finance, and by our National and State governmental processes.

We believe that the uncertainties associated with the "probability of causation" or "assigned share" methodology and the tables produced are so substantial that they are not suitable at this time for determining eligibility for compensation or the amounts of compensation payable under privately funded compensation systems such as those governed by tort law, or workers' compensation laws. Any further weakening of the causal link between private sector activities and injury, sickness, or disease is likely to lead to greater unpredictability of costs and to limit insurance availability and affordability.

Thank you.

[The prepared statement of Mr. Schmalz and response to questions submitted by Senator Hatch follow:]

STATEMENT OF
AMERICAN NUCLEAR INSURERS
MUTUAL ATOMIC ENERGY LIABILITY UNDERWRITERS
NATIONAL ASSOCIATION OF INDEPENDENT INSURERS
AND THE
AMERICAN INSURANCE ASSOCIATION

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
AND THE
SUBCOMMITTEE ON NUCLEAR REGULATION
OF THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

JUNE 12, 1985

I am Richard Schmalz, Counsel to American Nuclear Insurers and Mutual Atomic Energy Liability Underwriters, the two Nuclear Pools that are commonly known as ANI and MAELU. With me today are Marguerite Shea, Assistant Manager of MAELU, and Joseph Marrone, Vice President and General Counsel of ANI. We are also authorized to speak today on behalf of the National Association of Independent Insurers and the American Insurance Association.

The Nuclear Pools, ANI and MAELU, provide property and liability insurance to nuclear power plants and their suppliers and contractors. The membership of the Pools includes about 300 domestic property and casualty insurance companies. The NAII and the AIA are associations of property and casualty insurers with a combined membership of nearly 500 companies. Workers' compensation and general liability insurance is a significant, important part of their business.

Property and casualty insurers world-wide share a deep interest in any proposal that could change substantially the ground rules for the payment of damages or compensation benefits under the tort law or workers' compensation systems. These systems are under great pressure to deliver compensation to more injured persons and in higher amounts than ever before. The increasingly heavy burden must be funded by private individuals or firms who look mainly to private insurers to spread and limit their risk. Of course, ultimately consumers must pay more for the goods and services they require.

Expansion in privately funded remedies which proceeds at too rapid a pace, which gets out of control or which contradicts sound fundamentals leads to unpredictability and to potential costs that, in many cases, cannot be absorbed. The insurance market acts as a barometer in gauging the impact of this expansion. When world-wide insurance markets retreat or nearly vanish, as they have in the case of many products and medical specialties, and for environmental pollution, it is a clear sign that our compensation system itself is becoming unpredictable.

The fundamental principle governing the tort system has been that full compensation, regardless of need or the existence of collateral sources of benefits, is paid where there is fault and there is fairly strong proof of a causal connection between the fault and the injury. We should note, however, that the strength of the proof is not nearly as high as that usually required by scientists for recognizing valid causal laws. The proof required in tort cases is merely more probable than not, or slightly more than 50%.

The trend in tort law for many activities is toward strict liability, which increases substantially the number of injuries that will be compensated. This change by itself can probably be absorbed, but when it is compounded with a substantial weakening in the strength of the causal connection, it is not possible to compensate individual tort claimants at the traditional tort "full compensation" standard without "breaking the bank". The process will naturally be accelerated if the traditional "full compensation" standard is enriched in scope, as it has been by several courts.

For workers' compensation a somewhat different balancing formula applies. Liability is always strict, but the benefits paid are generally more limited than full tort compensation. Nevertheless, the injury must arise out of and in the course of employment. There must be a causal connection.

The radioepidemiological tables that are the subject of this hearing bear directly on this crucial matter of the causal connection between misconduct on the one hand and injury actually caused by such misconduct to a specific individual on the other. The tables have been prepared and reviewed by respected scientists. And they have been subjected to independent review by other experts. As perceived by the Oversight Committee

> "The objective in developing such tables of 'probability of causation' was to provide the scientific basis for an eventual formula for compensating cancer victims who claimed that ionizing radiation was the source of their cancers."[1]

We have no doubt that the tables represent the best guidance that science can give on the basis of present knowledge. But the question is not whether the scientists have done the best that can be done, but whether the tables themselves, or the method by which they were produced, are useful for applying our present tort and workers' compensation systems to radiation injuries or for modifying these systems, or indeed for designing new general purpose, privately financed compensation systems.

This much larger question is of course not wholly a scientific matter. The scientists who prepared and reviewed the tables did not purport to advise how the tables were to be used for these purposes. The Ad Hoc Working Group which prepared the tables said:

> "We cannot, however, predict which individuals will develop cancer. Even after the cancer has developed, we cannot state with certainty whether it was caused by radiation, since it is usually impossible to differentiate cancers induced by radiation from those which occur 'normally' in the population."[2]

The Working Group notes an "important difference" between the more exact physical sciences and biology and medicine.

> "In physics a large number of well-tested and comprehensive theories exist to guide calculations, whereas in biology and medicine there are few well-established general and predictive theories and the systems are immeasurably more complex. This becomes particularly important for calculation of the probability that radiation caused a certain cancer when the dose of radiation was small. Such calculations are therefore subject to great uncertainty (see Chapter VII)."[3]

In Chapter VII the Working Group carried this thought farther.

> "Although we know much more about the effects of ionizing radiation than any other carcinogen, and much of the knowledge is quantitative in form, our present knowledge is far from complete, and the tables can be regarded as no more than a guide to causation in the particular case." [4]

The Oversight Committee on Radioepidemiological Tables discussed at some length in its review of the Working Group's report the numerous sources of uncertainty that arise from applying rough models to poorly understood biological processes with very little hard data. The Oversight Committee recommended further quantitative appraisal, such as a sensitivity analysis, to evaluate the many uncertainties. Their own limited investigations showed that

> "the use of different reasonable assumptions or methods can produce estimates of assigned share [probability of causation] that differ by a factor of 2, 4, or more from the Working Group's estimates

> when the latter are near 20%. ... For example, it may be possible to estimate that the assigned share is 20% for a particular situation and to conclude that that is best current scientific estimate of the true probability. But the uncertainty may be so great that the true assigned share could be 80% or 5%, and any tribunal that awards compensation will have to wrestle with the problem of settling claims when faced with such uncertainties."[5]

The Oversight Committee points out that the use of single numbers in the tables (as required by the Orphan Drug Act), rather than ranges, tends to cloud reality.

> "But to avoid discussion of uncertainties in a quantitative fashion may suggest to nonscientists an unrealistically high precision of scientific knowledge. The mere existence of tabulations of assigned shares, especially without accompanying quantitative expressions of their uncertainty, could stimulate unintended uses -- scientific or otherwise -- that would be in appropriate, given the actual state of uncertainty." [6]

Messrs Cox and Fiksel of Arthur D. Little, Inc. have also reviewed, at the Pools' request, the scientific validity of the "Probability of Causation" methodology and the additional practical uncertainties introduced by the choice of different models for representing underlying biological processes or arising out of such sources as sampling variability, propagation of error and population non-homogeneity. They were among the first to make clear that the ratios produced by the "Probability of Causation" method are not true probabilities in the mathematical sense, and that the use of such a name is misleading. This has also been clearly stated by the Oversight Committee, which has recommended the term "assigned share" as a substitute.

Unfortunately, the name "assigned share" is equally misleading because it embodies a non-scientific value judgment. The Oversight Committee correctly explains that the "assigned share" is not a unique property of an individual. It is rather the estimated excess cancer ratio of a group of which the individual is a member. This ratio is then assigned to each member of the group as a proxy for each individual's true "probability of causation" (which cannot be ascertained). The ratio is chameleon-like. Its numerical value depends on the choice of the subgroups forming the partition of the total population. The choice of partitions is not entirely a scientific matter, as the Oversight Committee is careful to state. Nevertheless, the Oversight Committee believes

> "Even though the number computed is not a probability, it is a reasonable way to apportion blame for the excess [cancers in the exposed group], and so we think of it as a 'share,' rather than a probability. This share is assigned to every member of the group, and so we prefer the expression assigned share."[7]

But if an assigned share depends on a subjective partition and represents the "average" of a group that is not homogeneous, it may not seem very reasonable or very scientific to those individuals whose compensation is less than what they believe they are entitled to. Insurers recognize this as similar to the problem they face in developing and applying rating classifications for automobile insurance. Those who live in the suburbs generally favor the classification system, while those who live in the cities do not. Insurers have encountered widespread claims of unfairness using a classification system analogous to that used to derive "assigned shares" even when they have an abundance of statistical data supporting not only the average subgroup probabilities but also their homogeneity. Similar supporting data are not available for the radioepidemiological tables.

And if the "assigned share" is determined by a method that can substantially overstate the true individual "probability", or excess risk ratio, by propagating potential errors from sources so numerous and troublesome as the Oversight Committee suspects to be present, then those who must initially foot the bill will find it hard to agree that it is "scientific" or "reasonable." If the errors were random and tended to cancel each other, that would be helpful, but insurers believe that bias is a real problem in administering compensation systems. They are invariably construed liberally in favor of the individual for the simple reason that the amount of compensation to be paid the individual is relatively small in relation to the total pool of funds available to pay compensation. The latter amount is frequently regarded as unlimited in general purpose compensation systems such as the tort law or workers' compensation systems. But if all doubts are resolved in favor of compensation in every individual case, then the aggregate compensation paid on the "assigned share" basis will substantially exceed that which might be computed on a less ambitious group basis or under the present tort system.

The re-design of compensation systems, or the design of new systems, particularly if they are to be funded by private means, is a more complex task than perhaps the epidemiologists realize, although the Oversight Committee's Report does contain a brief discussion of several relevant points. [8] There are, however, certain fundamentals that need careful consideration. Goals must be set and justified. Compensation levels must be consistent with the goals. And the system must be reasonably efficient in implementing the goals as compared with other possible methods.

The tables themselves represent a first step in a process that needs a great deal of attention, not only by epidemiologists but also by scholars working in the fields of economics, law and finance, and by our national and state governmental processes.

We believe that the uncertainties associated with the "probability of causation" or "assigned share" methodology, and the tables produced, are so substantial that they are not suitable at this time for determining eligibility for compensation or the amounts of compensation payable under privately funded compensation systems, such as those governed by tort law or workers' compensation laws. Any further weakening of the causal link between private sector activities and injury, sickness or disease is likely to lead to greater unpredictability of costs and to limit insurance availability and affordability.

Notes:

1. ASSIGNED SHARE FOR RADIATION AS A CAUSE OF CANCER, Final Report, Oversight Committee on Radioepidemiological Tables (herein cited as Oversight Committee Report), Preface.
2. REPORT OF THE NATIONAL INSTITUTES OF HEALTH AD HOC WORKING GROUP TO DEVELOP RADIOEPIDEMIOLOGICAL TABLES (herein cited as Working Group Report), Executive Summary, page ii.
3. Working Group Report, Executive Summary, page iii.
4. Working Group Report, page 79.
5. Oversight Committee Report, page 116.
6. Oversight Committee Report, page 117.
7. Oversight Committee Report, page 31.
8. Oversight Committee Report, pages 127 - 130.

QUESTIONS FOR MR. SCHMALTZ FROM SENATOR HATCH:

1. Mr. Schmaltz, in a sense, the insurance industry pioneered statistical evaluations and epidemiology. It was the insurance industry that gave us life tables. The insurance industry lives by risk assessments. Therefore, I find the adamant opposition of the nuclear insurers to the NIH methodology perplexing, especially in light of the fact that a lack of predictable exposure is the very thing that is most lethal to insurers. Is the current chaos in the courtroom really preferable to evaluations based on the regularized methodology of the NIH report?

2. Does your organization object to the courts giving any credence to the NIH report? Do you have any alternate scientific means for assessing causality that might lend regularity to the courts' consideration of radiogeniccancer claims?

AMERICAN
NUCLEAR
INSURERS

BURT C. PROOM, CPCU
President and Chief Executive Officer

OFFICE OF THE GENERAL COUNSEL
Joseph Marrone
Vice President and General Counsel

August 23, 1985

Senator Orrin G. Hatch, Chairman
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Dear Senator Hatch:

This is in response to your questions concerning my recent testimony before the Senate Labor and Human Resources Committee.

Question 1.

You state that, in a sense, the insurance industry pioneered statistical evaluations and epidemiology. While the insurance industry is certainly interested in both improved statistical methods and epidemiology, I don't think we can take credit for "pioneering" in these areas.

You are quite correct that the insurance industry lives by risk assessments. In making such assessments, credible statistics and statistical methods of analysis are invaluable to the industry. On the other hand, putting numbers in tables without observing high standards of credibility does not improve the quality of risk assessment from an insurer's point of view. In fact, it may detract from the process by introducing substantial bias.

You cite the life tables as an example of how the insurance industry's risk assessments are aided by statistics. I am sure you will agree that the life tables have been constructed in a far different manner and on the basis of far greater actual experience than the radioepidemiological tables that were the subject of the recent hearing. And of course they do not pretend to predict any individual specific result, such as when any particular person will die.

The same may be said about the statistical data bases that are used to develop premiums for property and casualty insurance. We have a much richer body of actual experience to work with than was available to the scientists who prepared the radioepidemiological tables.

And we use these statistical data banks for a much less ambitious purpose than that proposed for the tables. We use the data to set individual premiums, which are usually but a small fraction of the average serious bodily injury loss. If we are off in a few instances by a small margin the financial impact is not great, and any larger aggregate variations can be verified and adjusted by the constant stream of new data. The PC methodology, however, takes a small amount of empirical data and combines it with a substantial amount of unverifiable assumptions to arrive at a result that is both hypothetical and uncertain. Thus, the result cannot be regarded as valid statistical data.

The radioepidemiological tables are designed to determine eligibility for individual compensation. Average death case values can be conservatively estimated at $500,000. The oversight committee of scientists who reviewed the Working Group's report point out that a table "probability" of causation of 20% could actually be as low as 5% or as high as 85%. And the method is such that when there are multiple causes of cancer, the result for each cause can vary widely, depending on which cause is calculated first.

Such a methodology, while perhaps the best that science can do on the basis of present knowledge, seems to the layman, at least, not in keeping with the usual high standards of science. At any rate, claims adjudicated on such a basis are not likely to be any more predictable than under the present tort system. In fact, the use of tables may well produce loss experience substantially higher than what we are currently seeing.

Thus, from an insurance point of view, which is primarily concerned with the predictability of losses over successive short terms for the purpose of setting annual premiums, the methodology of the NIH report would at best substitute another, possibly more substantial set of uncertainties, for those we presently face.

Question 2.

This leads directly to the first part of your second question. The nuclear pools will have to deal with court use of the tables on an ad hoc basis, as will everyone else. We doubt that they will find general acceptance. With error factors as high as four or more, we expect that the tables will produce even more disputes than arise at present.

We do not believe that it is now possible to develop any sound, general scientific method for determining the probability that any individual cancer was caused by a specific exposure to lowlevel radiation.

Although the nuclear pools have not attempted to devise alternative compensation systems, it seems clear that the best approximation consistent with historic tort law goals would be to retain the present "more probable than not" standard for individual cases, to apply this standard strictly and to provide a "public purpose" remedy where the expected incidence of cancer has been significantly increased.

I think all scientists will agree that the calculation of group incidence rates based on empirical observations are likely to be far more accurate than the PC's produced by the NIH or similar methodologies. This would permit a group payment for the public benefit consistent with the harm caused, even though it is impossible to identify the individual victims.

Such an approach would enhance the predictability of the tort system for the private sector generally, as well as for the insurance industry. It would be more likely to encourage a vigorous private insurance market.

Very truly yours,

Richard Schmalz

Richard A. Schmalz

Staff [presiding]. Well, gentlemen, it seems you have been left with the midnight shift.

Dr. **Fiksel**. I would like to add a few additional comments, if I might.

Staff. Certainly, Dr. Fiksel.

Dr. **Fiksel**. Some of the other points that I wished to make—and I did abbreviate my previous comments—are as follows.

The working group's efforts, while quite considerable, have to be regarded as consisting of two separate parts. One part is the accumulation of risk estimates, which are essentially projections of potential cancer incidents due to radiation exposure. The second part of their work is the construction of a formula which purports to provide a probability, and I think we should look at those efforts separately.

The first effort was very difficult, and there was clearly a great deal of uncertainty attached to it. However, it at least is a scientific enterprise, and we can evaluate the results on a scientific basis.

The second portion of their work, namely, the construction of the formula, is not truly a scientific exercise. It really involves a policy choice as to what type of attribution or allocation of blame is appropriate for a potential contributing cause of cancer.

As I said earlier, radiation cannot be singled out as "the cause" of any cancer; it can only be regarded as one potential contributing cause. And so it becomes a policy question as to the degree or the share of the excess risk that should be attributed to radiation. And there are several different formulae that have been proposed. The formula that the working group used is not unique in any sense, does not have any intrinsic scientific merit. It seems intuitively reasonable, but there are other formulae that have been advanced that have an equal amount of reasonableness.

I also would like to point out that the approach utilized by the working group involves something called a multiplicative interaction model. The multiplicative interaction model assumes that the effects of radiation multiply together with the effects of other factors that are present.

Now, there really is no basis for that. It is an assumption, and the working group points that out. There is evidence pro and con as to whether the effects of radiation in combination with other factors are additive, multiplicative, or have some other relationship. Since there is not enough scientific evidence, the working group chose to make this assumption, and I believe primarily because it simplifies the calculation; it enables them to calculate a PC without worrying about the background factors for a given individual. This simplification will tend to increase the relative share that is attributed to radiation. It inflates the amount of the PC to the extent that if you actually try to apply the PC formula to several different causes, or to all the contributing causes, you would get a great deal more than 100 percent of the total share. That in itself seems to be a conceptual flaw.

In addition, I have mentioned the tremendous uncertainties. According to our calculations, the potential range of uncertainty in application of the formula, for a typical PC, could be anywhere from zero to 90 percent if you really look at all of the factors involved. And therefore, a particular choice of PC which is a so-called "best estimate" really is not a very reliable way of allocating compensation.

So in conclusion, we would suggest that the PC formula cannot really be relied upon as a compensation mechanism because it will not provide consistent results, and when applied to a particular individual, it really may have very little correlation with the actual degree to which radiation contributed to that individual's cancer.

Thank you.

STAFF. Thank you, Dr. Fiksel.

As I started to say, you have been sort of left with the cleanup crew, and we are sorry for that. But this is the nature of the U.S. Senate, and you sort of know what they have to contend with and we in the background have to contend with all the time.

I would very much like to ask you some questions, but it is not particularly proper, and therefore, I think we would submit them in writing.

I will only make a very short editorial comment, and that is that one of the arduous aspects of our task always is to try to understand what everybody is saying and is going to say so that we can help facilitate our Senators' understanding. And on this issue, this general issue, it has been exceptionally and exceedingly difficult, and I have spent many hours pondering your report, what it means and what you are trying to say.

And we will submit questions for the record, both Senator Simpson and Senator Hatch. And with that——

Dr. FIKSEL. One additional comment, with reference to your comment. Imagine yourself being a judge or a juror——

STAFF. That is right. That is precisely, precisely, what this project is all about, because it is so difficult for a judge and a jury.

Dr. FIKSEL. These PC tables will not simplify the task of the judge or jury. If anything, they will make it more complex.

STAFF. Thank you, for your testimony Dr. Fiksel.

At this point we will insert into the record all additional statements subsequently submitted to the committee for to these hearings.

[Additional material supplied for the record follows.]

STATEMENT BY
A. N. TSCHAECHE, CERTIFIED HEALTH PHYSICIST
TO THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
AND THE
SUBCOMMITTEE ON NUCLEAR REGULATION OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
In The Matter Of The Use Of The National Institute of Health Report Containing "Probability of Causation" Tables Prepared In Response to Section 7(b) Of the Orphan Drug Act

I sympathize with Senator Hatch's attempts to provide a remedy for individuals who have developed a cancer and seek monetary assistance in treatment for that cancer with the thought that exposure to ionizing radiation caused that cancer. I do not agree that the "Probability of Causation" Tables prepared by NIH as directed by Section 7(b) of the Orphan Drug Act can reasonably be used to determine, estimate or even to guess that a particular cancer in a particular individual was causally related to an exposure of the whole body to ionizing radiation in the range of zero to 50 Rem or of any organ to an exposure in the range of zero to 500 Rem. Further, I do not agree that the probability that such cancers are causally related to such exposure can presently be determined based on any human experience.

In my experience, "science" does not know but can only hypothesize that values such as are given in the NIH report prepared in response to Section 7(b) of the Orphan Drug Act (hereafter called "The Report") are truly the correct values. The truth is we do not know the shape of the dose-effect curve for low doses (less than 50 Rem whole body) of ionizing radiation.

It is appropriate for Congress to base transfer of monies among individuals on an unproven hypothesis? Is it appropriate for Congress to point a causative finger at radiation on the basis of such an hypothesis? I suggest that it is not. It is time that scientists emphasized to Congress the truth, namely: that values in the report are no better than educated guesses based on an unproven hypothesis and as such should not be any kind of basis for monetary compensation. If any compensation for cancer victims is needed, a more reasonable approach would be for Congress to establish a fund from which all cancer victims would be paid. We don't even know the real cause(s) of cancer yet. How can we point a causative finger at ionizing radiation without at the same time pointing at chemicals, sunlight, stress and perhaps a myriad other causes?

I urge the members of the Committee and Subcommittee to set aside The Report until such time as it is known on the basis of human experience (not on hypothetical grounds) that low doses of radiation do cause cancer (not pre-cancerous lesions or changes in DNA or tumors or any of the other biological changes that some hypothesize are precursors to cancer.) I think a political solution to the cancer compensation problem is the only rational approach at present. "Science" can't help yet.

I am even more concerned that The Report as it presently exists will be publicized and may even be used in radiation injury claims cases. I do not think that the information in The Report should be used either to show no or little causation or to show a high or 100%, causation of cancer by doses below 100 Rem whole body. Therefore, I suggest that Congress place The Report in limbo, not endorse it or use it in any way. Such action would help in preventing what otherwise might be gross miscarriage of justice (on either side) in radiation injury claims cases.

KMC Inc

June 10, 1985

The Honorable Orrin G. Hatch
Chairman
Committee on Labor and Human Resources
Room SD-428
Dirksen Senate Office Building
First & Constitution Ave., N.E.
Washington, D.C. 20510

SUBJECT: June 11 and 12, 1985 Senate Hearings on the NIH Probability of Causation Tables

Dear Senator Hatch:

KMC, Inc. is a consulting firm whose clients are electric utilities with nuclear generating plants. KMC presently is sponsoring a utility group which is working on issues relating to radiation protection. Through this effort, KMC became aware of, and has followed with interest, the Senate hearings which addressed the concept of "probability of causation" and its possible use with regard to radiation injury claims, including the development and publication of the NIH Probability of Causation (PC) Tables.

We have prepared a written statement commenting on some aspects of the use of these tables in the legal system which we believe have not previously been discussed. We hope these comments will be helpful to you in your consideration of the NIH PC tables and request that our statement be incorporated into the record of the June 11 and 12 hearings.

We conclude that Congress should refrain from enacting any legislation which would incorporate the NIH PC tables into either the tort or workers compensation systems. If, however, Congress means to consider legislation regarding the use of the tables, we suggest that Congress consider using the tables as a screening device to preclude the filing of radiation injury claims which do not meet some statutory minimum PC value. While we do not recommend that Congress require the use of the NIH PC tables as one of several means employed by experts in determining whether a particular cancer is radiation induced, if Congress takes this action, the PC tables should be modified to take into account the characteristics of the plaintiff and his family in order to arrive at the best estimate.

If we can be of any assistance, please let us know.

Sincerely,

Donald F. Knuth

Donald F. Knuth
President

KMC Statement on the Use of the NIH Probability of Causation Tables in the Legal System

Introduction

In March 1985, the National Institutes of Health ("NIH") published its "Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables" pursuant to the Orphan Drug Act, Public Law 97-414. Section 7(b) of the Orphan Drug Act required the Secretary of Health and Human Services to devise and publish radioepidemiological tables stating as a single percentage a probability of causation, for doses ranging from 1 millirad to 1,000 rads, of developing radiation-related cancer. At the outset, we would like to acknowledge the difficulty of that assignment. NIH has struggled with many uncertainties and constraints in its attempt to present the best available scientific evidence on radiation exposure in the form of probability of causation ("PC") tables. Its report identifies these difficulties. The reservations expressed in this statement are not criticisms of scientific efforts to develop a PC methodology but rather are concerns about the use of that methodology.

Section 7(b) of the Orphan Drug Act does not mandate any particular use or application of the NIH PC tables. The tables were undertaken, at least in part, to demonstrate that there exists a much greater scientific consensus on the health effects of ionizing radiation than most laymen realize. The NIH tables and accompanying report have accomplished this result. In this regard, the NIH Report concluded that "[a]s a public health problem, ionizing radiation ranks well down the list of carcinogens: less than 3% of the U.S. cancer burden can be plausibly attributed to ionizing radiation from natural sources and human activities" (NIH Report, page 13). As this goal of stating scientific consensus has been accomplished, Congress need not find additional uses for the NIH PC tables. Based on the considerations stated below, Congress may quite legitimately refrain from enacting legislation which would somehow incorporate the NIH PC tables into the legal system.

Different suggestions have been made to incorporate the NIH PC tables into the tort law and workers compensation systems by which radiation injury claims are resolved. These suggestions include using the tables (1) as a screening device to preclude the filing of radiation injury claims which do not meet some minimum PC value, (2) as an exclusive means of establishing causation in tort and/or workers compensation cases, and (3) as but one of several means used by an expert in determining whether a particular cancer is radiation induced.

PC Tables Cannot Substitute for Causation

In both tort and workers compensation cases, the law is concerned with redress of the individual. Thus, in order to use the NIH PC tables as a means of establishing causation, the NIH PC methodology must be able to state with a high degree of accuracy and certainty that a particular individual's cancer was caused by a particular exposure to radiation. The authors of the NIH tables admit, however, that "the tables can be regarded as no more than a guide to causation in the particular case" (NIH Report, page 79).

To understand this limitation on the ability to use the NIH PC tables for establishing causation, it is helpful to quote more extensively from the NIH Report:

> It is not possible to tell whether or not a particular cancer observed in a given individual following exposure to ionizing radiation was caused by that exposure. . . . We often can tell, however, if the number of cancers observed in a group of exposed people is greater than the number that would have been observed in the absence of exposure and, if so, we can estimate roughly how many of the observed cancers were induced by radiation.

(NIH Report, page 17). The difficulty of establishing a simple cause-and-effect relationship between radiation and cancer in an individual has given rise to the probability of causation method. While implicitly acknowledging that a given cancer may have been caused by any of a number of factors acting alone or in combination, the method assigns to the dose of radiation received a share of causation, based on available epidemiological data. To illustrate, if a given dose of radiation has been observed in epidemiological studies to increase the incidence of a particular type of cancer by ten percent above the spontaneous incidence, then the probability of causation is taken to be about ten percent for the individual who has contracted that cancer. Thus, the NIH PC methodology does not attempt to determine causation. Instead, it calculates the ratio of radiation-induced excess cancers to total cancers in a population and applies that ratio to an individual as a share of causation.

To apply this rough estimate of the number of radiation-induced cancers in a group to the determination of whether an individual's cancer was radiation induced is to engage in speculative extrapolation. An individual will have unique values bearing on cancer incidence, e.g., age, sex, personal habits (smoking, alcohol, diet), occupation, medical history (x-rays, drugs), and family history of cancer. Due to these unique values, an individual cannot be accurately represented by the populations from which the incidence data are drawn. Moreover, except for sex and age, these key values bearing on cancer incidence will be largely unknown to those making the PC calculation. Because the NIH PC tables simply apply as a share of causation a ratio of radiation-induced excess cancers to total cancers in a population, the NIH PC tables should not be used as the sole means of establishing causation.

Legal Considerations

Congressional action mandating the use of the NIH PC tables as a means of establishing causation could have unintended effects on our legal system. First, such action would substitute a statistical method of calculating a ratio of cancer risks and appling that ratio as a share of causation for proof of causation in fact. This would be a profound break with current law. The substitution of a statistical method of calculating a share of causation for proof of causation in fact will most likely increase the number of claims brought and awards made as it will expand the eligibility of plaintiffs.

To gain some approximation of the number of possible claims that might be brought in the tort and workers compensation systems, keep in mind that there have been approximately 300,000 badged workers at commercial nuclear power reactor sites since 1957. Based on average statistics for the U.S. population, about 30 percent of this group would be expected to develop cancer and about 16 percent would die of cancer.

With regard to this group of approximately 300,000 badged workers, two cases are useful for illustration: a) the Nuclear Regulatory Commission legal limit for workers of 5 rem per year and b) the nuclear power industry average of about 0.8 rem per year (NUREG/CR-4160, p.B.4). If the age at which an individual begins working in the nuclear power industry is 18, the working period 20 years, and the age when cancer is diagnosed 50 years, the following table shows the PC value derived from the method and tables of the NIH Report:

Cancer	Probability of Causation	
	0.8 rem/y	5 rem/y
Acute leukemia	10.5%	43.0%
Lung cancer:		
non-smoker	7.7%	35.1%
smoker	0.8%	5.3%

Based on U.S. cancer mortality rates (1977), roughly 0.007 percent of the general population of white males, aged 50-54, will develop leukemia of any type each year. At the rate of 0.007 percent and for a population of 300,000 workers, 105 leukemias would be expected to appear between the ages of 50 and 54. Within this group of 105 leukemias, each nuclear power plant worker who had received the assumed 5 rem a year would have a 43.0 percent PC value.*/ If used as a means of establishing causation, the NIH PC tables would provide a large number of workers with an avenue for seeking compensation from the nuclear power industry for their leukemias. Thus, the table illustrates the potential for an increase in the number of claims because individuals who have received legally-permissible exposures may in fact have relatively high PC values.

Second, although proponents of the PC approach argue that use of the PC tables will be an automatic and simple method of establishing causation, it may also introduce uncertainty into the claims resolution process, at least at the outset, as the methodology has not previously been used on a widespread basis. Use of PC tables in resolving radiation injury claims may also introduce uncertainty into the resolution of claims alleging injury from other carcinogens as parties, judges, and boards may attempt to use the approach. While science does not yet have sufficient data to undertake PC calculations for toxic chemicals, legislators should expect this situation to change as continuing research on the carcinogenecity of such chemicals is developed. In that event, the NIH PC tables could serve as a model for establishing causation in cases involving chemical carcinogens. Congressional action mandating the use of the NIH PC tables as a means of establishing causation should thus be carefully considered.

---

*/ This calculation can be done for each type of cancer which contributes to the 30 percent incidence rate.

Third, Congress should consider the relationship between the use of PC values as a statistical method of calculating a share of causation and the burden of proof employed in radiation injury claims. Under present law, a plaintiff must establish that his injury was more probably than not caused by defendant's conduct. In practice, this has meant that 51 percent of the evidence adduced must support plaintiff's position. Once requests for damages or compensation are based on a 51 percent PC value, it is not a long step to requests based on, for example, a 33 percent PC value. Even if the recovery permitted is limited to a pro rata share of total damages, the potential for more and larger claims is great due to a lesser burden of proof and the possibility of inflated damage estimates. As Congress has recently begun to examine ways to curb the excesses in product liability litigation, care should be taken not to introduce the possibility of such excesses in the litigation of radiation injury claims.

Policy Implications

Because radiation is the most studied and best understood carcinogen, science can determine excess radiation-induced cancers in a population. Sufficient data does not exist to detect excess cancers for most other carcinogens at this time. This imbalance in the amount of available data may suggest that radiation is a very serious carcinogen. This is not, in fact, the case. As noted earlier, radiation accounts for less than three percent of the U.S. cancer burden.

Despite this scientific knowledge, Congress has required the development and publication of tables stating the "probability" that radiation in the millirad range causes cancer. Such Congressional action, in the absence of equivalent action concerning more potent carcinogens such as tobacco, creates the impression in the public mind that radiation is to be feared. Such fear results in improper decision-making in wide-ranging areas such as personal decisions regarding proper medical treatment (x-rays), governmental decisions concerning safe energy sources (nuclear power), and individual choices of employment (a very risky chemical environment versus a much less risky radiation environment). In determining whether to incorporate the NIH PC tables into the legal system, Congress should keep in mind these adverse effects on sound decision-making. In this regard, it is instructive to quote from the National Council on Radiation Protection Report No. 43:

> Undue concern, as well as carelessness with regard to radiation hazards, is considered detrimental to the public interest.

No Need for Legislation

Some might argue that, while the above concerns are valid, some courts and boards have already admitted evidence on probability of causation approaches or have ignored the issue of proof of causation altogether. The fact that this has happened does not mean that these are good decisions or that similar future decisions are inevitable. In the past, courts and boards have issued incorrect decisions and have enunciated bad principles of law. Ordinarily, the legal system corrects such results on its own. Decisions are reversed on appeal; scholarly articles are written criticizing bad principles of law. The same corrective process can be expected to take place in the area of radiation injury claims. Indeed, in Johnston v. U.S., 597 F. Supp. 374 (D. Kan. 1984), the court rejected the probability of causation approach, finding that proof of causation must be founded on more than theory or hypothesis.

With regard to the belief that courts and boards have not handled radiation injury claims well and that the adversary system confuses courts, boards, and juries by presenting them with differing expert opinions, it is important to realize that mere development and publication of Federal PC tables will not eliminate confusion and differing expert opinions in such cases. Different positions will be taken by plaintiffs and defendants as to the weight to be attached to the tables as evidence. In all likelihood, plaintiffs and defendants will differ on the correctness of the factors that go into the NIH PC formula and on the correctness of the formula itself.

This conclusion is supported by the fact that several different PC methodologies, based on essentially the same data used by NIH, have already been used as evidence in radiation injury claims before courts, juries, and workers compensation boards. In such cases, for example, defendants have used PC calculations to argue that the probability a plaintiff's cancer was caused by his radiation exposure is quite small while plaintiffs have used PC calculations to argue that the probability is much higher. Plaintiffs have also challenged the dose amounts being used in the PC calculations by defendants, alleging that the amounts are grossly understated.

Conclusion

In sum, we recommend that Congress refrain from enacting any legislation which would incorporate the NIH PC tables into either the tort or workers compensation systems. If, however, Congress means to consider legislation regarding the use of the tables, we suggest that Congress consider using the tables as a screening device to preclude the filing of radiation injury claims which do not meet some statutory minimum PC value. While we do not recommend that Congress require the use of the NIH PC tables as one of several means employed by experts in determining whether a particular cancer is radiation induced, if Congress takes this action, the PC tables should be modified to take into account the characteristics of the plaintiff and his family in order to arrive at the best estimate.

FOR THE:
U.S. SENATE COMMITTEE
LABOR & HUMAN RESOURCES
HEARING ON RADIOEPIDEMIOLOGIC TABLES

ROSALYN S. YALOW
JUNE 11, 1985

We live in a world in which the perception of reality is too often confused with reality and there are few fields in which more confusion exists than in the popular perception of the hazards of exposure to low level radiation and low level radioactive wastes. Much of the fear of radiation has been generated by the association of radiation and radioactivity with nuclear explosions and nuclear war. So phobic is this fear that the new medical imaging modality "nuclear magnetic resonance" or NMR has been renamed by physicians Magnetic Resonance Imaging or MRI in order to avoid the bad word "nuclear".

I believe that Public Law 97-414 which requires "the Secretary of Health and Human Services to devise and publish radioepidemiologic tables... These tables shall show a probability of developing each radiation cancer associated with receipt of doses ranging from 1 mrad to 1000 rads" is a disservice to our people in that it creates a mind-set in the public that radiation at the mrad level is a cause for concern. Since 1 mrad is about 1% of natural annual background and a round trip flight from Washington, D.C. to Los Angeles increases radiation exposure by 5 mrad, most of us would accept that the probability of causation of cancer at dosages in the mrad range is obviously zero to many significant figures. In fact, living in Utah compared to living in Washington results in an increase in natural background radiation exposure of 40 mrad per year or about 3 rads for those who live the biblical three score and ten years. Should one evacuate Utah to avoid this additional 3 rad background radiation exposure? Of course it must be appreciated that, because of the lovely marble columns, those working in the U.S. Capitol receive an additional exposure of 20 mrad per working year. There are regions in the world where natural background is 10-fold higher (~1 rad/year or 70 rad/lifetime) and the gamut of possible deleterious health effects have been looked for and not found.

Properly used, the Radioepidemiologic Tables should serve to demonstrate that people working in the nuclear industry or those serving as crews on transcontinental or intercontinental flights have a risk from their occupational radiation exposure that is trivial compared to the risks associated with daily living. In fact, although there have been the typical industrial accidents, such as an electrical fire at the Indian Point reactor that resulted in the deaths of three workers, there has never been a single fatality from a radiation accident in an American commercial nuclear power plant. In 1978 the Council on Scientific Affairs of the American Medical Association reported in a "Health Evaluation of Energy-Generating Sources" that occupational deaths and diseases from the total coal fuel cycle for generation of electricity was 10-fold greater than those for the total nuclear fuel cycle. This is the type of comparison that should be made in considering the risks associated with radiation exposure.

In a 1981 Report to the U.S. Congress by the Comptroller General of the U.S. General Accounting Office on "Problems in Assessing the Cancer Risks of Low-Level Ionizing Radiation Exposure" it was concluded that "there is as yet no way to determine precisely the cancer risks of low-level ionizing radiation exposure, and it is unlikely that this question will be resolved soon". Stating that there are levels below which one cannot discern harmful effects of radiation is not the same as reaching conclusions concerning the existence of a threshold below which radiation effects in man does not occur. In science we can only accept as valid those laws that are subject to experimental proof. We can hypothesize, but we should not confuse hypothesis with reality. There is a problem in determining what kinds of studies should be funded in radiologic research. It is evident that epidemiologic studies cannot produce meaningful data about the existence of a threshold for radiation effects. Molecular and cellular studies may or may not give some insight about molecular or cellular effects but cannot answer important questions about repair mechanisms in the intact animal or man when radiation is delivered at low dose-rates. At present there are no really good ideas that would permit a breakthrough in the field of low-level radiation effects. Therefore, good scientists with imagination and insight are unlikely to work in a field in which the studies, at best, are pedantic and, at worst, are inevitable flawed. Thus, this field of research which is now primarily generated not by scientific interest but by Federal concern and Congressional mandate is not likely to attract investigators seeking to open new frontiers in science.

The question must seriously be addressed as to whether the time and effort to update the Radioepidemologic Tables, as is required by the present law, would be well-spent. Until there is, if ever there will be, a breakthrough that would overturn the cumulative experience of 80 years of study of the biologic effects of radiation, any corrections to the Tables would have a trivial effect in changing the probability of causation of cancer at the doses and dose rates to which radiation workers and the general population is exposed. Money and resources for science could and should be spent in a more useful fashion to assure the health and well-being of our people. I urge this Committee and our Congress to pay attention to the science rather than the politics generated by popular misperception in dealing with radiation-related issues.

Staff. The hearing is now adjourned.

[Whereupon, at 12:25 p.m., the joint hearing was adjourned.]

○